INTEGRATED MEDICAL SYSTEMS, INC.

LIFE SUPPORT FOR TRAUMA AND TRANSPORT (LSTAT)

MODEL 9602B

Part No. ALBX0300J003 Rev A

USER MANUAL

FOR USE WITH LSTAT DDLS AND SECONDARY
DISPLAY SOFTWARE VERSION 1.3

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CHAPTER 1 OVERVIEW

1.1 System Overview

LSTAT is a portable individual intensive care unit for resuscitation, stabilization and evacuation of trauma casualties. The unit travels with the casualty and serves as the interface to the various evacuation vehicles that transport the individual to definitive care at a hospital or other medical care facility. LSTAT operates in an austere forward environment and in static rear areas, either in a temporary stand-alone posture or while utilizing existing power, oxygen and medical air resources. Figure 1-1 shows an overall view of the LSTAT.

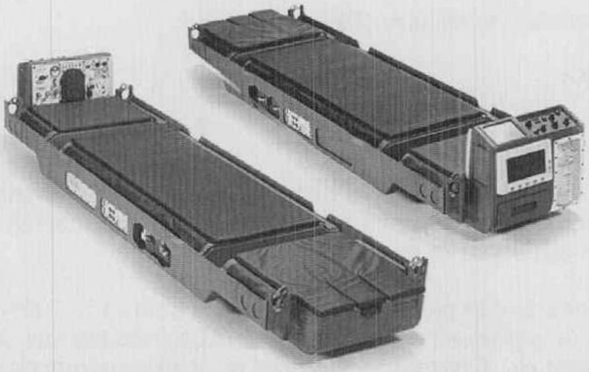


Figure 1-1. LSTAT View

LSTAT includes an onboard Physiological Monitoring Unit, Suction Unit, Defibrillation Unit, Fluid Administration Unit, Ventilator, Oxygen Subsystem, self contained Power Source and Electrical Power Subsystem, Internal Environmental Control Subsystem, Portable Clinical Analyzer, and Display and Data Logging Subsystem.

1.1.1 Physiological Monitoring

The LSTAT has the capability to monitor the patient status and functions continually and to report those anomalies that occur with the patient to the operator. Monitoring functions include: Non-Invasive Blood Pressure, two channels of Invasive Blood Pressure, Electrocardiogram (ECG), Pulse Oximetry (SpO_2), Airway Carbon Dioxide (CO_2), Airway flow and Volume, and Temperature (esophageal or skin). Each of the measured parameters is range checked and the alarm condition posted as necessary. The monitored information is delivered to the Display and Data Logging Subsystem (DDLS).

1.1.2 Suction Unit

The Suction Unit is designed for removing secretions from the upper airway during oropharyngeal, nasopharyngeal and tracheal suctioning procedures; programmable gastrointestinal and abdominal wound drainage; or surgical site debris removal in field hospitals.

1.1.3 Defibrillator

The semi-automatic defibrillator monitors and analyzes a patient's Electrocardiogram (ECG) to apply defibrillation shocks, when required. The ECG analysis circuitry assesses the electrode conditions and signal waveform. When lethal arrhythmias are detected, the defibrillation circuitry is automatically charged and an advisory is issued that the defibrillation pulse should be applied. If the operator authorizes the discharge, then the discharge is applied through the patient electrodes. If the operator fails to authorize the shock application to the patient within 30 seconds, then the charge is dumped into an internal dummy load. Patient ECG and response to counter shock are recorded.

1.1.4 Fluid/Drug Infusion

The multichannel infusion pump delivers resuscitation levels of intervenus solutions and multiple drugs at rates from .1 to 999 cc/hour on each of its three channels. The pump has its own 6-hour nickel cadmium battery to function in the absence of LSTAT power. The unit reports fluid types, rates and related information to the Display and Data Logging Subsystem.

1.1.5 Ventilator

The ventilator system contains an electronically controlled ventilator, compressor, and air/oxygen mixer to supply the patient with medical grade air and oxygen. It is controlled by an internal microprocessor that continuously monitors and displays airway pressure, control settings, alarm parameters, gas source, gas flows, gas blends and power signals. An adjustable pressure limit control limits peak inspiratory pressures and high-pressure alarm set point. Automatic ventilator backup assures continued mechanical support if the patient becomes apneic. A Manual Breath button permits manual delivery of ventilation at any time.

The ventilator operates in one of three modes.

Synchronized Intermittent Mandatory Ventilation (SIMV).

Assist Control Ventilation (ACV).

Continuous Positive Airway Pressure (CPAP).

ACV, SIMV, and CPAP modes are operable with or without Positive End Expiratory Pressure (PEEP) and are altitude compensable to minimize the patient's work-of-breathing. External (45 - 55 psi) medical air hook ups are also provided on either side of the LSTAT.

The ventilator provides gas mixtures with oxygen content ranging from 21 to 100%. Gases may be blended from external oxygen (compressed gas cylinder or PTLOX) and internal compressor, or external oxygen and external compressed air. External compressed air, delivered from an electric compressor, must be oil less and filtered. Acceptable input gas pressures may range up to 60 psi without affecting measurement accuracy or danger of internal components. The ventilator is operable through the LSTAT electrical system and does not consume gas for operating power. All gas is dedicated for patient care.

Ventilator features include:

- Automatic monitoring of LSTAT generated power, internal compressor and external gases.
- Extensive alarm monitoring of operating, non-operating and advisory conditions.
- Gas efficient electronic control circuitry to eliminate pneumatic-logic circuits and dependency on gas for operating power.
- May be operated with and without attachment of external gas.
- Numeric panel markings to indicate sequence-of-operation steps to simplify and speed start-up.
- Graphics display with 12-second pressure waveform. Amplitude is calibrated to the adjacent digital bar graph.
- Automatically compensates pressure transducer to altitude related barometric pressure changes up to 25,000 ft.

1.1.6 Oxygen System

The oxygen system provides oxygen to a gas blender to mix with ambient air for the ventilator. An internal oxygen bottle has the capacity to hold 480-liters of oxygen at 3000 psi and deliver 8 liters per minute for 1 hour.

Ports located on both sides of LSTAT (Figure 1-2) permit connection of an external oxygen supply of 40-55 psi. When external oxygen is used, flow from the internal oxygen bottle stops. A ventilator bypass oxygen port is available on the LSTAT head fairing for connecting a cannula or a mask. There is no oxygen flow regulation at the bypass port, so flow regulation is accomplished using a flow regulator attached to an external tube on the oxygen mask.

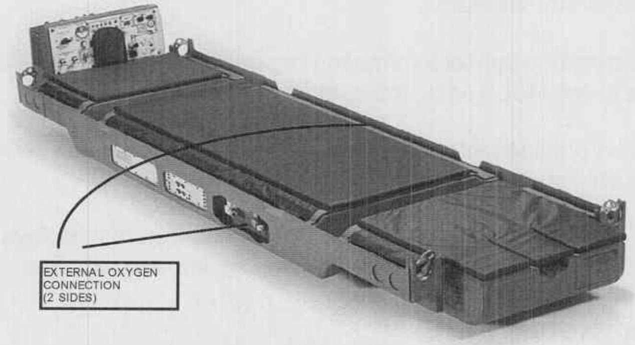


Figure 1-2. External Oxygen Ports

The internal oxygen bottle is removable for replacement or refill. The bottle assembly includes the high-pressure bottle, a shut-off valve and a mechanical pressure gauge, viewable through a transparent window in the foot compartment (Figure 1-3). Internal oxygen bottle capacity is continuously available from the pressure gauge or LEDs on the Operator/Patient Interface Panel. In addition to internal capacity, LEDs are provided to indicate low or high internal oxygen bottle pressure and to identify when external oxygen is being supplied.

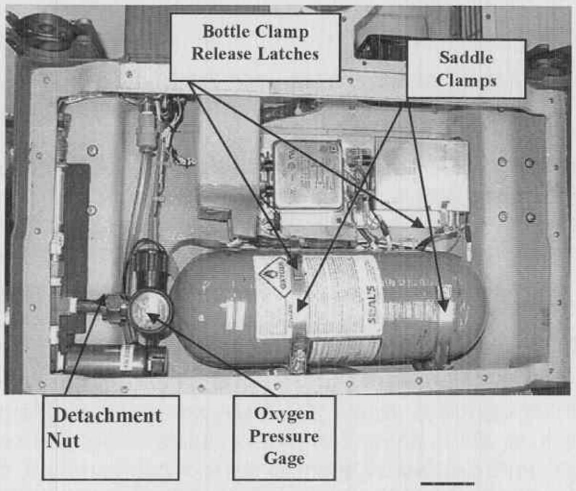


Figure 1-3. Internal Oxygen Bottle Assembly

1.1.7 Display and Data Logging Subsystem (DDLS)

The Display and Data Logging System (DDLS) records physiological data for the patient and records status of LSTAT equipment. The DDLS logs data for up to 72 hours of continuous use.

At start-up, LSTAT performs an automatic built-in-test (BIT) to determine the operational health of the DDLS. The DDLS has two modes, Operational and Maintenance.

Operational Mode

The DDLS performs data logging functions and provides interactive displays and controls for an operator to view data or download logged data to an off-board computer.

Maintenance (MAINT) Mode

This mode is primarily used for parameter setting and data logging. The operator enters the maintenance mode during start-up. The operator can transition from maintenance to the operational mode.

The DDLS consists of three operator interfaces:

DDLS Indicator Panel to ascertain essential information regarding the functionality of the DDLS, and provide essential commands to the DDLS (e.g., reset, lamp test, etc.)

Data Entry and Display Panel provides information about the DDLS status and health, as well as providing the operator with a vehicle to input patient session information.

Secondary Display provides secondary displays of the LSTAT subsystems displays with integrated information and a capability to input more informative annotations into the data log.

1.1.8 Electrical Power System (EPS)

The LSTAT EPS interfaces with auxiliary power from multiple evacuation and air/ground-based environments utilizing five separate adapters. It also has the capability to be re-charged/re-energized and can operate autonomously for at least 30 minutes. High performance Nickel-cadmium batteries are used and can be recharged in place and/or exchanged. The power system can operate from the following external power sources:

115±10% VAC 60Hz ±5 Hz 1 Phase
108 to 118 VAC 400 Hz ±7Hz 1 Phase
230±10% VAC 50 Hz ±3 Hz 1 Phase
25 ±5 VDC

In austere circumstances where portable generators are used the LSTAT requires at least 1 KW, 120 Volts AC to operate.

The EPS provides a smooth uninterrupted transition between self-powered and auxiliary modes. See Figure 2-5 for external electrical connections. Controls are provided for managing any power source and support the automatically controlled recharging of self-contained power stores during periods of AC auxiliary power connection. Recharging can be completed within a 24-hour time span for a completely discharged system.

1.1.9 Environmental Control

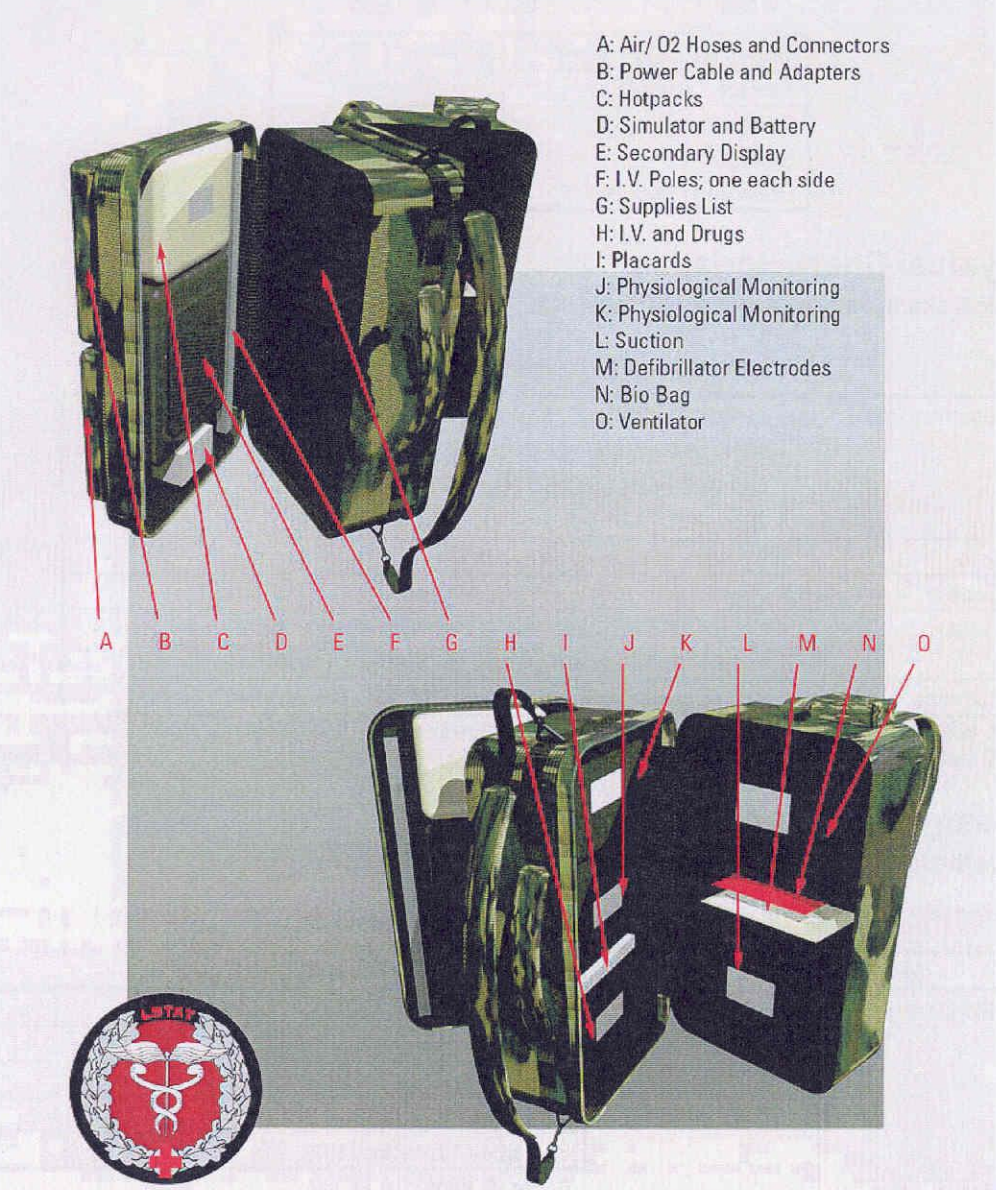
The Environmental Control System (ECS) provides LSTAT equipment with clean filtered air at temperatures below +40 ^{0}C with air velocities above 100 ft/min, when ambient temperatures are above +25 ^{0}C, with no condensed moisture. Air is brought in through inlets located on either side of the head fairing and is exhausted through vents located adjacent to the foot compartment. System over temperature conditions are indicated on the side mounted ECS indicator panels and transmitted to the DDLS as well. Various distributed critical and typical sled locations are monitored with temperature sensors and recorded by the DDLS as well.

1.1.10 Portable Clinical Analyzer

Blood chemistry or cerebral fluid chemistry analysis is accomplished with a handheld, portable unit and has the capability to perform various blood testing. Blood cerebral fluid testing is accomplished by the use of disposable cartridges that are inserted with the sample into the instrument for analysis. The Portable Clinical Analyzer can perform blood tests for sodium, potassium, chloride, glucose, urea nitrogen, hematocrit, ionized calcium, arterial blood gases, (pH, PCO_2, and PO_2), and bicarbonate. In addition, certain other values, such as carbon dioxide, base excess, anion gap, hemoglobin and O_2 saturation, can be derived by calculation from the tests performed. The Portable Clinical Analyzer operates on two (2) 9 V lithium batteries, can store up to 50 patient records and can transmit individual or groups of records via infrared signals (IR) to the DDLS. Data can also be viewed on the analyzer screen itself.

1.1.11 Accessory Bag

LSTAT includes an accessory bag containing a supply of disposable and reusable items. The contents of the bag are fully described in Appendix D. A supply list is provided for inventory and refilling purposes. Figure 1-4 shows the accessory bag and its contents.


A: Air/ 02 Hoses and Connectors
B: Power Cable and Adapters
C: Hotpacks
D: Simulator and Battery
E: Secondary Display
F: I.V. Poles; one each side
G: Supplies List
H: I.V. and Drugs
I: Placards
J: Physiological Monitoring
K: Physiological Monitoring
L: Suction
M: Defibrillator Electrodes
N: Bio Bag
O: Ventilator
A
B
C
D
E
F
G
H
I
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K
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M
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LSTAT

Figure 1-4. Accessory Bag

1.2 Intended Use

The LSTAT is intended to be used in compliance with the instructions in the LSTAT documentation and according to accepted hospital and clinical protocols. The LSTAT is to be used only with accessories and other parts as contained in the LSTAT documentation. Use of other than recommended or supplied accessories and parts may result in inaccurate patient information and possible damage to the LSTAT.

The LSTAT is intended for use on adults weighing 90 lb. or more.

The LSTAT is intended to be used by medically qualified personnel trained to operate the medical subsystems of the LSTAT.

1.3 Environmental Conditions

LSTAT is designed to operate in a "relatively controlled" environment. The system contains an ECS system for internal cooling, and can operate under the environmental conditions listed in Table 1-1.

Table 1-1. Environmental Conditions

Operating Temperature	+10 °C to +40 °C
Storage Temperature	0 °C to +40 °C
Relative Humidity Storage Operating (Planned)	 15% (6 hr.) 95% 29 °C (4 hr.)

1.4 Physical Characteristics

LSTAT physical characteristics are listed in Table 1-2.

Table 1-2. LSTAT Physical Characteristics

Electrical Power*	115 VAC±10% VAC, 60 Hz ±5 Hz, 1 Phase 108-118 VAC 400 Hz ±7Hz 1 Phase 230 VAC±10% VAC, 50 Hz ± 3Hz, 1 Phase 25±5 VDC
Size	13" high, 85.5" long, 22" wide
Cooling	Internal ambient air for components
Weight	173.66 LB. (with stretcher, O2 bottle and regulator) 151.84 LB. (without stretcher, O2 bottle and regulator)
Batteries	Rechargeable Nickel-Cadmium (NiCad) - greater than 30 min.

* In austere environments where portable generator power is provided, a minimum of 1 KW 120 Volts AC is required to operate the LSTAT.

1.5 Measurements and Treatments

Table 1-3 lists the basic measurements and treatments of the LSTAT.

Table 1-3. Measurements and Treatments

Subsystem	Measurement/Treatment
Physiological Monitoring	Electrocardiogram (ECG)
	Blood Pressure (Non-Invasive)
	Blood/Intracranial Pressure (Invasive)
	Temperature
	End tidal and inspired CO_2
	Apnea Events
	Breath Rate
	Pulse Oximetry
	Ventilatory Pressure and Flow
Blood Chemistry Analyzer	Blood chemistry Assessment
	Blood Chemistry calculated
Suction	Continuous and Intermittent Modes
	Reservoir accessible inside outer mold line
Defibrillator	Automated external defibrillator, preprogrammed, paste on electrodes
Intravenous (IV) Fluid and Drug Administration	Three independent flow pumps
Ventilator	Mandatory Assist modes
	Ventilation Parameter Controller
	Onboard Medical Air Supply
	Onboard Air/O_2 Blender
	Gas inputs
	Ventilation parameters

Subsystem	Measurement/Treatment
	Physiological/Performance Numeric displays
	Physiological/Performance Waveform display
	Altitude Compensation
	Adjustable Pressure Thresholds
	Adjustable Alarm Sources
	Non-adjustable Alarm Sources

1.6 Maintenance Documentation

Circuit diagrams, component parts lists, descriptions, calibration instructions or other information which would assist the users appropriately qualified technical personnel to repair those parts of equipment that have been designated by Integrated Medical Systems as repairable are available on request.

1.7 Inquiries, Comments, Requests for Parts and Complaints

Inquiries, comments, parts requests or complaints regarding the LSTAT should be forwarded to:

Integrated Medical Systems, Inc.
1984 Obispo Avenue
Signal Hill, CA 90804
support@lstat.com

CHAPTER 2 SYSTEM OPERATION

2.1 LSTAT Setup

2.1.1 Equipment

Check that the following equipment is installed on the LSTAT system:

1. Unopened defibrillator electrode pad set attached to the defibrillator ELCTD connector.
2. Two patient restraining straps (under the patient pad).

> NOTE
>
> Defibrillator electrode pads must be connected prior to turning the defibrillator on or an error will occur.
>
> If LSTAT has been in storage for 6 months or more, the oxygen bottle must be installed. Refer to Oxygen Bottle Replacement (Section 12.5.7).

2.1.2 Accessories

All LSTAT accessories are located in the accessory bag.

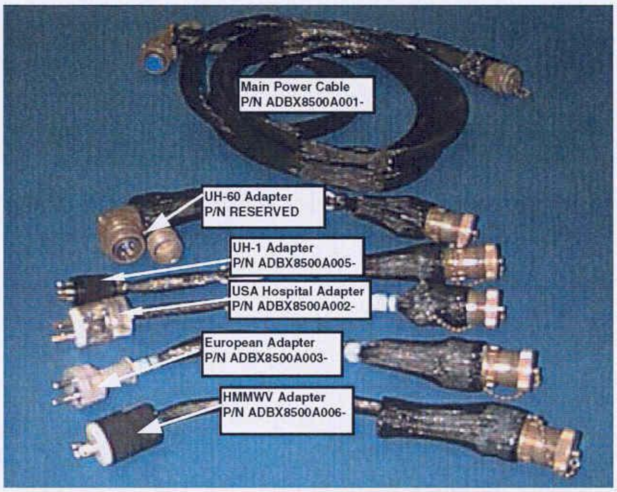

Main Power Cable
P/N ADBX8500A001-
UH-60 Adapter
P/N RESERVED
UH-1 Adapter
P/N ADBX8500A005-
USA Hospital Adapter
P/N ADBX8500A002-
European Adapter
P/N ADBX8500A003-
HMMWV Adapter
P/N ADBX8500A006-

Figure 2-1. Electrical Cable and Adapters

2.1.3 Checkout Procedures

1. Remove LSTAT from the shipping container.
2. Store the container in a controlled area to preclude damage or loss.
3. Inspect the LSTAT for visible signs of damage.
4. Inspect LSTAT for proper connections and equipment setup (refer to Operator's Shift Checklist, Appendix L).
5. Record damages or missing equipment on Operator's Shift Checklist or similar form

2.1.4 Pre-use Cleaning

2.1.5 Charging the Batteries

If LSTAT was in storage more than 6 months (long-term storage) without electrical power, recharge the batteries before using.

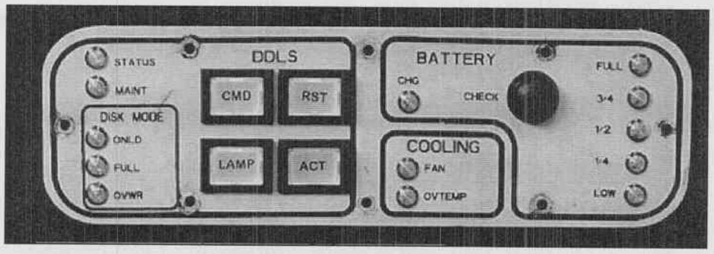


Figure 2-2. Indicator Panel

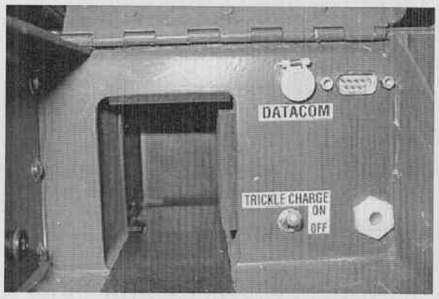


Figure 2-3. Trickle Charge Switch

1. Press the BATTERY *CHECK* button on the Indicator Panel for battery capacity (Figure 2-2). The Indicator Panel is located on either side of LSTAT. When fully charged the FULL light will illuminate.
2. Verify all subsystem Power controls are in the *OFF* position and that LEDs are not lit.
3. Verify the *SYSTEM POWER* switch on the Operator/Patient Interface Panel is *OFF*.
4. Connect LSTAT to external power utilizing the appropriate power adapter supplied in the accessory bag. Follow external power-on procedures (Section 2.2.3)
5. Toggle the *TRICKLE CHARGE* switch in the foot compartment (Figure 2-3) to *ON*.
6. When fully charged, toggle the *TRICKLE CHARGE* switch to *OFF*.
7. Disconnect external power.

NOTE

Battery charge may be terminated at any time without degrading the battery.

Recharging can be completed within a 24-hour time span for a completely discharged system..

Allow a longer charging time for new batteries.

2.1.6 Warm-up

1. Toggle the *SYSTEM POWER* switch to *ON*.
2. Wait 35 seconds for the system to power up.
3. Observe LEDs on the Operator/Patient Interface Panel briefly illuminate.
4. Observe *SYSTEM POWER PWR* LED is lit.
5. Observe the STATUS LED on the Indicator Panel is on and Green.
6. Press the *CHECK* button on the BATTERY Panel for battery capacity.
7. Observe the INTERNAL OXYGEN SUPPLY on the Operator/Patient Interface Panel. Verify ¼, ½, ¾, and FULL LEDs are illuminated. If FULL is not illuminated, replace the oxygen bottle (Section 12.5.7).
8. Remove the footpad.

9. Observe the oxygen pressure is 3000 psi. If less than 3000 psi, replace the oxygen bottle (Section 12.5.7).
10. Turn on each LSTAT subsystem.
11. Verify that no error messages are displayed. If errors are displayed refer to each chapter for the subsystem that has errors.

2.1.7 Setting Date and Time

1. Press the *CMD* and *RST* button on the Indicator panel to get into the MAINTENANCE mode on the DDLS Indicator Panel.
2. Press and hold the *LAMP* button on the Indicator Panel until the message, "MAINTENANCE MODE SET TIME" appears on the Data Entry and Display Panel display.
3. Observe the MAINT light on the Indicator Panel turns on yellow.
4. Press *ENTER* on the Data Entry keypad.
5. Press the number keys on the Data Entry keypad to enter the hour (format is 24-hour time hh:mm:ss). The cursor automatically advances to the minutes.
6. Press the number keys on the Data Entry keypad to enter the minutes. The cursor automatically advances to the seconds.
7. Press ZERO button (0) twice to enter seconds.
8. Press the *ENTER* button to set the time.
9. Press *FWD* once to see the message "MAINTENANCE MODE – SET DATE" appear.
10. Press *ENTER* on the Data Entry keypad.
11. Press the number keys on the Data Entry keypad to enter the month (format is 01 for Jan, 02 for Feb, etc). The cursor automatically advances to the day.
12. Press the number keys on the Data Entry keypad to enter the day. The cursor automatically advances to the year.
13. Press the number keys on the Data Entry keypad to enter the year. LSTAT is Y2K compliant, so entering 00 for 2000 will be correctly interpreted.
14. Press the *ENTER* button to set the date.
15. Press *FWD* until the Data Entry and Display Panel display reads "MAINTENANCE MODE ***GO OPERATIONAL***".
16. Press *ENTER* on the Data Entry keypad and note the Data Entry and Display Panel display reads "***GO OPERATIONAL*** PRESS ENT TO OPERATE".
17. Press the *ENTER* button twice to restart the DDLS.
18. Observe the MAINT light on the Indicator Panel is off.
19. Observe the STATUS light on the Indicator Panel is green

2.1.8 Enter Patient ID

On the Data Entry and Display Panel:

1. Observe the MAIN MENU is displayed. Press FNC key twice to return to the MAIN MENU from any other screen.
2. Press 1 on the keypad to display the INPUT MENU.
3. Press 2 on the keypad to display the Patient ID screen.
4. Enter up to 20 digits using the keypad numbers. Press FWD or BCK to move the cursor to overwrite data.
5. Press ENT to accept new Patient ID number.
6. Press FNC and BCK to return to the INPUT MENU.

Refer to Table 3-3 for a complete list of DDLS Data Entry and Display Panel screens and functions.

2.2 System Operation

Internal Batteries or an External Power source powers the LSTAT system. The two-position *SYSTEM POWER* toggle switch located on the Operator/Patient Interface Panel controls power to the LSTAT (Figure 2-4). When power is applied the green *PWR* LED is illuminated. If internal power is used then the amber *BAT* LED is also illuminated. The SYSTEM POWER control also provides power to the Data Display and Logging System, and Environmental Control System. The medical subsystems are controlled by separate power controls.

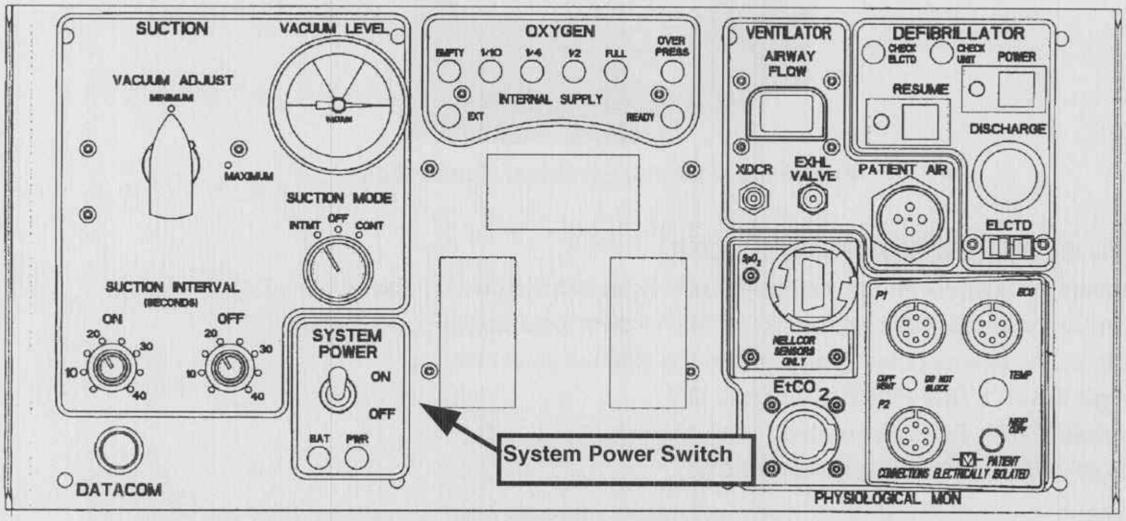

SUCTION
VACUUM LEVEL
VACUUM ADJUST
MINIMUM
MAXIMUM
VACUUM
SUCTION MODE
INTMT
OFF
CONT
SUCTION INTERVAL
(SECONDS)
ON
OFF
20
30
10
40
20
30
10
40
SYSTEM POWER
ON
OFF
BAT
PWR
DATACOM
OXYGEN
EMPTY
1/10
1/4
1/2
FULL
OVER PRESS
INTERNAL SUPPLY
EXT
READY
System Power Switch
VENTILATOR
AIRWAY FLOW
XDCR
EXHL VALVE
PATIENT AIR
DEFIBRILLATOR
CHECK ELCTD
CHECK UNIT
POWER
RESUME
DISCHARGE
ELCTD
SpO2
NELLCOR SENSORS ONLY
EtCO2
P1
ECG
CUFF VENT
DO NOT BLOCK
TEMP
P2
NIBP CUFF
PATIENT CONNECTIONS ELECTRICALLY ISOLATED
PHYSIOLOGICAL MON

Figure 2-4. System Power Switch

2.2.1 Internal Power

1. Press the BATTERY *CHECK* button on the Indicator Panel (Figure 2-2).
2. Observe BATTERY LEDs indicate a usable charge level.
3. Toggle the *SYSTEM POWER* switch to *ON* (Figure 2-4).
4. Observe *PWR* LED is illuminated.
5. Observe the BAT LED is illuminated.

> **IMPORTANT**
>
> Frequently monitor the BATTERY LEDs on the Indicator Panel when using internal battery power.
>
> If BATTERY indicates a *LOW* charge, connect the LSTAT into an external power source. Toggle the *TRICKLE CHARGE* switch to *ON*.

2.2.2 Switching from Internal Power to External Power

When external power is applied, internal batteries will automatically cease output.

1. Determine the external power source to be used.
2. Install the appropriate adapter on the power cable (Figure 2-1).
3. Connect the power cable to main power connector (figure 2-5).
4. Connect the power adapter into the external power source.
5. Toggle the *TRICKLE CHARGE* switch to *ON*.

2.2.3 External Power

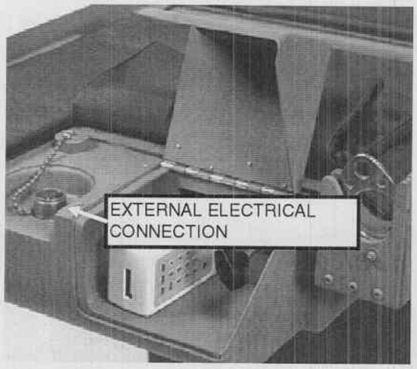


Figure 2-5. External Electrical Connection

1. Verify the *SYSTEM POWER* switch is *OFF*.
2. Connect the adapter for the available power source to the power cable (Figure 2-1).
3. Connect the power cable to the LSTAT Main Power Connector (Figure 2-5).
4. Connect the external power adapter into the external power source.
5. Toggle the *SYSTEM POWER* switch to *ON*.
6. Observe *PWR* LED is illuminated.
7. Toggle *TRICKLE CHARGE* switch to *ON*.

NOTE

LSTAT cannot Tickle Charge when using external DC power if the *SYSTEM POWER* switch is *OFF*.

Internal batteries will charge with the *TRICKLE CHARGE* switch *ON* or *OFF* when *SYSTEM POWER* is *ON* and connected to external AC power.

The BATTERY *CHG* LED on the Indicator Panel will illuminate when using external AC power.

2.2.4 Switching from External Power to Internal Power

When external power is removed the internal battery power automatically turns on.

1. Disconnect the power cable adapter from external power source.
2. Disconnect the power cable from LSTAT.
3. Observe the *SYSTEM POWER BAT* LED is illuminated.
4. Clean the external power cable and its adapter before repackaging. Cleaning instructions are described in Section 12.2.9.

2.3 Environmental Control System

The Environmental Control system provides internal ventilation for LSTAT and is automatically activated when *SYSTEM POWER* is switched *ON*. See note in Section 2.6.

1. Observe the green FAN light on the Indicator Panel is on.
2. Observe the OVERTEMP light is not on.
3. Feel for vibration caused by the fan motor.

2.4 System Shutdown

WARNING

TURN OFF THE OXYGEN SUBSYSTEM BEFORE TURNING OFF SYSTEM POWER.

1. Turn off each subsystem.
2. Toggle the *SYSTEM POWER* switch to *OFF*.

If using an external power source:

3. Disconnect the LSTAT power cable/adapter from the external source.
4. Disconnect the power cable from the LSTAT connection.
5. Clean the external power cable and its adapter.

2.5 Power Diagnostics

Electrical Power failure indications are evidenced from the *SYSTEM POWER* LEDs and the Battery Panel LEDs indicating charge levels. Table 2-1 is provided for "hands-on" diagnosing of electrical problems.

Table 2-1. Power Diagnostics

Indication	Condition	Corrective Action
LSTAT Connected into external power, power switch on, no power or battery indications.	1. Possibly no power to external outlet being used. 2. Possible use of incorrect adapter. 3. Adapter or main power cable may have malfunctioned. 4. Possible Dead battery 5. Possible AC to DC converter failure. 6. Circuit Breakers "blown".	1. Check if there is power to external outlet. 2. Check to see if correct adapter used or if damaged. 3.If there is power and the adapter is correct and not malfunctioning, then the problem is internal. 4. Check Circuit breakers in Foot compartment. If out, then push in. Re-start LSTAT. 5. If situation persists, contact IMS support.
External Power removed, LSTAT switched to battery power, no power or battery indications.	1. Batteries dead. 2. Possible internal wiring failure. 3. Circuit Breakers "blown".	1. Switch back to external power as dictated by medical situation. 2. Re-charge or remove and replace batteries as dictated by medical situation 3. Check Circuit breakers in Foot compartment. If out, then push in. Re-start LSTAT. 4. If situation persists after recharging then contact IMS support
Main power switch on, Green light on, Indicator Panel lights not on.	1. Signal not getting to Panel 2. Internal wiring failure. 3. Bad LED's.	1. Verify other side of LSTAT. If O.K. then continue. 2. Restart LSTAT. 3. If there is no change and/or both sides are dead then contact IMS support.
Head Fairing Battery light LED amber, but no battery power.	1. Possible dead battery. 2. Possible internal wiring failure. 3. Possible bad LED's.	1. Restart the LSTAT. 2. Attempt to power on individual subsystems. If successful then LSTAT conditionally O.K. to use. 3. Verify charge status on indicator panel.

2.6 Environmental Control (ECS) Diagnostics

Red or Green LED's will register an over temperature condition and/or Fan on condition when it is operating. Table 2-2 is provided for "hands-on" diagnosing of ECS peculiar problems.

NOTE: The ECS fan only operates above 50°F, so the fan not operating is not necessarily a failure.

Table 2-2. ECS "Hands-on" Diagnostics

Indication	Condition	Corrective Action
Intake air flow weak	Fan not functioning properly or filter clogged.	Remove and replace filter. If airflow does not improve, contact IMS support.
Exhaust air flow weak	Fan not functioning properly or filter clogged.	Remove and replace filter. If airflow does not improve, contact IMS support.

Indication	Condition	Corrective Action
LSTAT on, Red light on ECS Display panel	Fan inoperative	If temperature is below 50°F or the LSTAT was just brought in from a colder than 50°F environment, the fan does not need to run. If not, contact IMS support
LSTAT on, no air flow no Green light.	Failed Fan or LED circuit.	Contact IMS support.

CHAPTER 3 DISPLAY AND DATA LOGGING

Press and hold the *LAMP* button on the Indicator Panel until the message, "MAINTENANCE MODE SET TIME" appears on the Data Entry and Display Panel display.

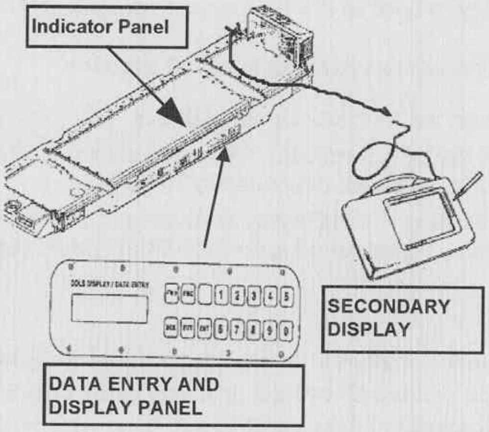

Indicator Panel
DDLS DISPLAY / DATA ENTRY
ENT
1
2
3
4
5
6
7
8
9
0
SECONDARY DISPLAY
DATA ENTRY AND DISPLAY PANEL

Figure 3-1. DDLS Panels and Displays

3.1 Intended Use and Limitations

The Display and Data Logging System (DDLS) is designed to display and record patient data. The Indicator Panel, Data Entry and Display Panel and the Secondary Display (Figure 3-1) are designed to operate together or stand alone to provide up to date patient information. The Secondary Display is discussed in CHAPTER 11.

3.2 Equipment

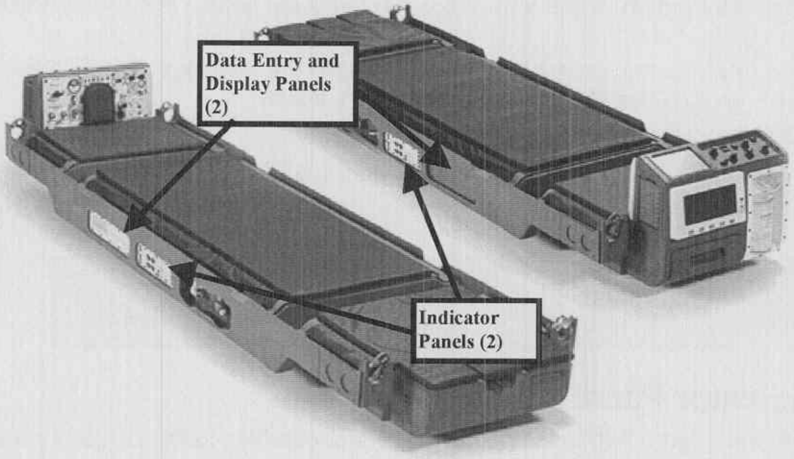

Data Entry and Display Panels (2)
Indicator Panels (2)

Figure 3-2. DDLS Interface Panels

3.3 Accessories

Use the accessories listed in Appendix D and where called out in this section.

3.4 DDLS Operation

3.4.1 DDLS Power-On

DDLS automatically turns on whenever LSTAT *SYSTEM POWER* is switched ON.

1. Toggle *SYSTEM POWER* to *ON*.

LSTAT will have a 10-second delay to boot as the ECS system purges LSTAT of any residual gases.

The DDLS will run a Self-Test. This will last approximately 30 seconds.

2. Check that the STATUS light on the Indicator Panel is green.

See Table 3-1 for a description of the DDLS indicator lights and colors. If STATUS is not green, perform any required action using the control functions described in Table 3-2.

3. Observe the Data Entry and Display Panel Display turns on and the MAIN MENU is displayed (Table 3-3). The Data Entry and Display Panel remains on until *SYSTEM POWER* is switched *OFF*.

3.4.2 Automatic Self-Test

Upon power-up, the DDLS will invoke a diagnostic testing component of the subsystem perform initial power-up test of the DDLS. The diagnostic test will test all external interfaces of the DDLS as well as its internal interfaces. Testing for the Secondary Display is not part of this diagnostic test, but is performed separately upon its own power-up. If the power-up diagnostic test of the DDLS does not find any sub-unit or component failure, then the DDLS will by default transition to the normal mode of operation. If the diagnostic test does find a failure with one of the components, the DDLS will still transition to the normal mode of operation (e.g., in cold weather the hard drive may take longer to become fully operational, but the displays may be operational immediately). The results of the diagnostic testing will be displayed on the Indicator Panel, with a separate indicator LED illuminating when the DDLS is operational. The DDLS can only test its interface with the other LSTAT subsystems. Individual LSTAT subsystems are checked out as they are powered-up, according to their individual self-test diagnostics.

3.4.3 View LSTAT ID

To view the LSTAT ID do the following:

1. Press the *CMD* and *RST* button on the Indicator panel to initiate getting into the MAINTENANCE MODE.
20. Press and hold the *LAMP* button on the Indicator Panel until the message, "MAINTENANCE MODE SET TIME" appears on the Data Entry and Display Panel display.
21. Observe the MAINT light on the Indicator Panel turns on yellow.
22. Press *FWD* until the display reads: MAINTENANCE MODE SET IP ADDRESS.
23. Press *ENTER* to view the LSTAT ID.

> NOTE
> The LSTAT ID is required with the use of the Secondary Display.

3.5 DDLS Indicator Panel

The DDLS Indicator Panel (Figure 3-3) is the primary Operator interface to the DDLS. It provides the essential information to the operator indicating that the system is operating properly. It also provides the essential command interfaces to the DDLS. The panel consists of five indicator lights, four buttons and a beeper.

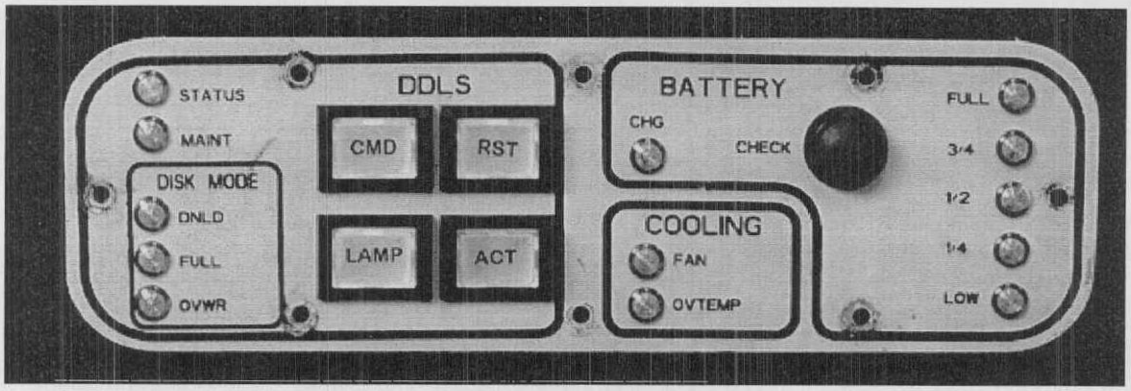


Figure 3-3. Indicator Panel

Table 3-1. Indicator Panel Light Status

INDICATOR	COLOR	DESCRIPTION
STATUS	GREEN	DDLS ON and fully operational.
	GREEN but flashes RED	DDLS ON but failed. Press RST to reset DDLS.
	RED	DDLS operating in a degraded mode and the hard drive is not functioning properly.
	NO COLOR	DDLS has failed its self-test. Press RST to reset DDLS. If situation persists the DDLS is non-functioning. The other subsystems may be operable.
MAINT	YELLOW	DDLS operating in the Maintenance State.
	NO COLOR	DDLS not operating in the Maintenance State.
DNLD	YELLOW	A remote device has been attached to the DDLS and is down loading data.
	NO COLOR	DDLS is not down loading.
FULL (INFO ONLY)	RED	The DDLS has logged data for almost 24 hours without a down load. Light stays on until download is initiated or the data storage device has been purged during maintenance procedures. This is a reserved task.
	NO COLOR	The disk has less than 24 hours of data stored.
OVWR (INFO ONLY)	RED	DDLS is beginning to overwrite previously logged data. This has happened because there is no free space on the disk. Down loading should be undertaken. This is a reserved task.
	NO COLOR	DDLS is not overwriting data.

Four DDLS control buttons are located on the Indicator Panel. Table 3-2 describes the DDLS control functions.

Table 3-2. Indicator Panel DDLS Controls

BUTTON	FUNCTION	OPERATION
CMD (Command)	Enables the RST button when CMD and RST are pressed together.	Press with RST button only.
RST (Reset)	Hard resets the DDLS CPU forcing a system reboot and initialization routines when pressed with the CMD button.	Press CMD button along with RST button for hard reset. Reset will not occur with only one button pushed.
LAMP	Conducts a lamp test of the Indicator Panel's LED's and the Data Entry and Display Panel Display/Keypad display. All LED's will illuminate (the CPU status will be green).	Press the LMP button for lamp test. Press and hold lamp button to go into the maintenance mode when initially powering up. "MAINT" will illuminate on the Data Entry and Display Panel.

BUTTON	FUNCTION	OPERATION
ACT	Used to conserve power by disabling LED's when operator is not using the display, or is using secondary display	Press button to activate LED's. Press button again to de-activate LED's.

3.5.1 Beeper

The beeper is located within the Indicator Panel. The beeper is sounded if the error is in the Indicator Panel or the Data Entry and Display Panel.

3.6 Data Entry and Display Panel

The Data Entry and Display Panel provides Operator interface functionality beyond that of the indicator panel. It is not essential for running the basic functions of the DDLS. The display will indicate and specify the health of LSTAT.

3.6.1 Display and Format

The Data Entry and Display Panel is located adjacent to the Indicator Panel (Figure 3-3), located closest to the head of LSTAT. The Data Entry and Display Panel (Figure 3-4) includes:

- A display with two lines of up to 20 alphanumeric characters.
- A data entry keypad with 5 function keys (plus one key for future functionality) and 10 numeric keys.

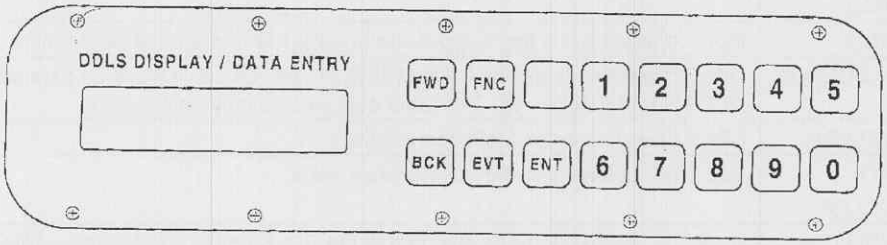


Figure 3-4. Data Entry and Display Panel

3.6.2 Data Entry and Display Panel Operation

The Data Entry Panel Display includes a series of screens accessed from menu options. Table 3-3 describes the screens and functions of the Data Entry and Display Panel.

Table 3-3. Data Entry and Display Panel Function

SCREEN	DISPLAY	OPERATION
MAIN MENU	LSTAT MODEL 9602VX.X 1) INPUT 2) STATUS 3) ? (Where X.X is the version of DDLS software)	• Appears at Start up. • Press 1 on the keypad to display the Input Menu. • Press 2 to display the Status Menu. • Press 3 for Help using the display functions. • Press FNC key twice any time to return to the Main Menu.
INPUT MENU (Option 1 from MAIN MENU)	INPUT MENU - 1)EVENT 2)PATIENT ID 3) OP ID	• Press 1 to display last event with date and time. • Press 2 to enter new Patient ID. • Press 3 to enter new Operator ID. • From any INPUT screen, press FNC and BCK to return to the INPUT MENU. • From the INPUT MENU, press FNC and BCK to return to MAIN MENU.

SCREEN	DISPLAY	OPERATION
EVENT Screen (Option 1 from INPUT MENU)	EVENT number mm/dd/yy hh:mm:ss or EVENT NONE If no events have been entered	• Displays the last registered event number with date and time. • Press ENT to generate a new event number. • Each time the ENT key is pressed a new event is generated. • Date and time stamp created by the DDLS. • Press the EVT key from any screen to display the EVENT screen. • Press FNC and BCK to return to the INPUT MENU.
PATIENT ID Screen (Option 2 from INPUT MENU)	ENTER PATIENT ID	• Enter up to 20 digits using the keypad. • Press FWD or BCK to move the cursor to overwrite data. • Press ENT to accept new Patient ID number. • An invalid input will cause a tone to sound. • Press FNC and BCK to return to the INPUT MENU.
OP ID Screen (Option 3 from INPUT MENU)	ENTER OPERATOR ID	• Enter up to 20 digits using the keypad. • Press FWD or BCK to move the cursor to overwrite data. • Press ENT to accept new Operator ID number. • An invalid input will cause a tone to sound. • Press FNC and BCK to return to the INPUT MENU.
STATUS Menu (Option 2 from MAIN MENU)	STATUS MENU 1) ERROR 2) TIME 3) DDLS 4)I/F	Provides access status screens. • Press 1 to display error log. • Press 2 to display current date and time. • Press 3 to display DDLS Menu. • Press 4 for I/F. • Press FNC and BCK to return to MAIN MENU.
ERROR screen (Option 1 from STATUS MENU)	If no errors the screen will display: ERROR LOG NO ERRORS If any errors were detected, the screen will display: ERROR LOG *SUBSYSTEM* REGISTERED AN ERROR	Indicates subsystems that have data errors. • Each error will be displayed for 5 seconds. • Press FNC and 2 to immediately display the subsystem I/F Status screen for any displayed error. • Press FNC and BCK to return to STATUS MENU.
TIME Screen (Option 2 from STATUS MENU)	LSTAT MODEL 9602VX.X mm/dd/yy hh:mm:ss	Allows Operator to view date and time. • Press FNC and BCK to return to STATUS MENU.
DDLS MENU (Option 3 from STATUS MENU)	DDLS MENU 1)DATA LOG 2)REMOTE I/F 3)GEN	Allows Operator to access DDLS status screens for input. • Press 1 for DDLS disk log status. • Press 2 for REMOTE I/F. • Press 3 for general DDLS status. • Press FNC and BCK to return to STATUS MENU.
DATA LOG Screen (Option 1 from DDLS MENU)	DDLS LOG STATUS DISK IS *XX*% FULL	• Press FNC and BCK to return to DDLS MENU.
Remote I/F Screen (Option 2 from DDLS MENU)	Not Available	RESERVED

SCREEN	DISPLAY	OPERATION
General Status Screen (Option 3 from DDLS MENU)	Not Available	RESERVED
I/F Screen (Option 4 from STATUS MENU)	Not Available	RESERVED
Physiological Monitor Screen	Not Available	RESERVED-Monitor frequency of physiological monitor errors • Press FWD to advance to Ventilator Screen. • Press BCK to go to Sled Screen. • Press FNC and then BCK to return to STATUS MENU.
Ventilator Screen	Not Available	RESERVED-Monitor frequency of ventilator errors • Press FWD to advance to IV Pump Screen • Press BCK to return to Physiological Monitor Screen. • Press FNC and then BCK to return to STATUS MENU.
IV Pump Screen	Not Available	RESERVED-Monitor frequency of IV pump errors • Press FWD to advance to Blood Chemistry Analyzer Screen. • Press BCK to return to Ventilator Screen. • Press FNC and then BCK to return to STATUS MENU.
Blood Chemistry Analyzer Screen	Not Available	RESERVED-Monitor frequency of blood chemistry analyzer errors • Press FWD to advance to Suction Screen. • Press BCK to return to IV Pump Screen. • Press FNC and then BCK to return to STATUS MENU.
Suction Screen	Not Available	RESERVED-Monitor frequency of suction errors • Press FWD to advance to Defibrillator Screen. • Press BCK to return to Blood Chemistry Analyzer Screen. • Press FNC and then BCK to return to STATUS MENU.
Defibrillator Screen	Not Available	RESERVED-Monitor frequency of defibrillator errors • Press FWD to advance to Oxygen Screen. • Press BCK to return to Suction Screen. • Press FNC and then BCK to return to STATUS MENU.
Oxygen Screen	Not Available	RESERVED-Monitor frequency of oxygen errors • Press FWD to advance to Power/ECS Screen. • Press BCK to return to Defibrillator Screen. • Press FNC and then BCK to return to STATUS MENU.
Power/ECS Screen	Not Available	RESERVED-Monitor frequency of power/ECS errors • Press FWD to advance to Sled Screen • Press BCK to return to Oxygen Screen. • Press FNC and then BCK to return to STATUS MENU.

SCREEN	DISPLAY	OPERATION
Sled Screen	Not Available	RESERVED-Monitor frequency of sled errors • Press FWD to advance to Physiological Monitor Screen. • Press BCK to return to Power/ECS Screen. • Press FNC and then BCK to return to STATUS MENU.
HELP (?) MENU (Option 3 from MAIN MENU)	HELP MENU 1) HELP 2) HOT KEYS	Focal point for entering the help screens. • Press 1 for General Help • Press 2 for Hot Key List • Press FNC key twice any time to return to the Main Menu.
General Help (Option 1 from HELP MENU)	Screens provide a tutorial list for general help in navigating and using the Data Entry and Display Panel.	• Press FWD or BCK keys to scroll through general help screens.
Hot Key List (Option 2 from HELP MENU)	Press FNC, FNC to get to Main Screen. Press FNC-1 to get to Error Log. Press FNC-2 to get to REMOTE I/F (Status). Press EVT to get to Event.	Allows the Operator to short-cut to other areas: • Press FWD and BCK buttons to page through the list of hot keys.

3.7 DDLS Diagnostics

Basic diagnostic information for the DDLS is available on the Data Entry and Display Panel on the side of the LSTAT. Table 3-4 lists the indications, conditions and corrective actions for the Data Entry and Display Panel and Secondary Display and Data Logging/Data Loading failures.

Table 3-4. DDLS Diagnostics

Indication	Condition	Corrective Action
Indicator Panel		
No Light	DDLS has failed self-test.	1. Restart LSTAT. 2. If situation persists DDLS defective. However other subsystems may be operable.
LSTAT on, STATUS light off	Internal failure	Reset DDLS (up to 2 times). Check ACT button to ensure panel LEDs have been activated. If indication persists, contact IMS support.
DDLS on, one or more LEDs out.	Possible LED failure.	Perform lamp test. Check ACT button to ensure panel LEDs have been activated. If condition persists, contact IMS support.
LSTAT on, LEDs do not illuminate. Computer appears "on" when Secondary Display attached.	Lamp failure or ACT button not on.	Check rest of LSTAT subsystems. If "on" system is conditionally usable. If other failures present, contact IMS support.
Data Entry and Display Panel		
LSTAT on, display blank on one side of LSTAT.	Defective Panel	Check other Panel. If working then LSTAT conditionally operable. Otherwise, contact IMS support.
LSTAT on, Main screen lit, no buttons function	Defective Panel	Re-cycle power to LSTAT. If situation persists contact IMS support.

Indication	Condition	Corrective Action
EVT button does not function on one side.	Defective Panel	Check other Panel. If working then LSTAT conditionally operable depending on approval of Higher authority. Otherwise, contact IMS support.
FWD button does not function on one side.	Defective Panel	Check other Panel. If working then LSTAT conditionally operable depending on approval of Higher authority. Otherwise, contact IMS support.
BCK button does not function on one side.	Defective Panel	Check other Panel. If working then LSTAT conditionally operable depending on approval of Higher authority. Otherwise, contact IMS support.
ENT button does not function on one side.	Defective Panel	Check other Panel. If working then LSTAT conditionally operable depending on approval of Higher authority. Otherwise, contact IMS support.
FNC button does not function on one side.	Defective Panel	Check other Panel. If working then LSTAT conditionally operable depending on approval of Higher authority. Otherwise, contact IMS support.
LSTAT on, STATUS light green. Unable to menu through Display/Data Entry Panel	Failed Panel	Reset DDLS. If condition persists, contact IMS support.
Secondary Display		
Secondary Display power switch on, unit does not boot up.	No external power, No battery power	Ensure cable to Secondary Display connected. Connect LSTAT to external power Replace or recharge LSTAT batteries.
Secondary Display boots up but main screen does not appear.	Wrong Display Mode selected	Using stylus tap the display selecting Hot Pad. If nothing happens then contact IMS support.
Stylus does not work	Stylus does not have sufficient power to operate.	1. Change Stylus batteries (AAAA alkaline) 2. Change the Stylus tip. A. Grasp the stylus tip and pull it straight out of the stylus. B. Insert the new stylus tip into the stylus until it seats.
Secondary Display locks up	Internal failure	Reboot by pressing the recessed re-set button on the left side of the Secondary Display. If problem persists then remove and replace Secondary Display
Inaccurate or no Readouts	Poor Ethernet connection	Check Ethernet connection and re-seat if necessary. If situation persists, Replace Secondary Display.
Power Switch will not turn off Secondary Display	Broken power switch	Replace Secondary Display.
Data Logging/Download		
LSTAT on, no LEDs on, computer on, system has Data Logging/Down Loading capability.	Internal failure	Conduct lamp test. If indication persists, Remove and Replace indicator panel.
LSTAT on, STATUS LED green, no data/no down load occurs when secondary Display attached.	Internal failure with Secondary Display. LSTAT conditionally usable.	1. Check cable. 2. Remove and replace Secondary Display. If condition persists, Contact IMS support.

CHAPTER 4 PHYSIOLOGICAL MONITORING

4.1 Intended Use & Limitations

Do not operate at temperatures below +10°C or above +40°C.

Even though the physiological monitor contains fully isolated patient-connected circuitry, it has not been specially designed for direct cardiac application.

4.2 Equipment

4.2.1 Controls and Displays

The physiological monitor is made up of the following controls, display and connectors:

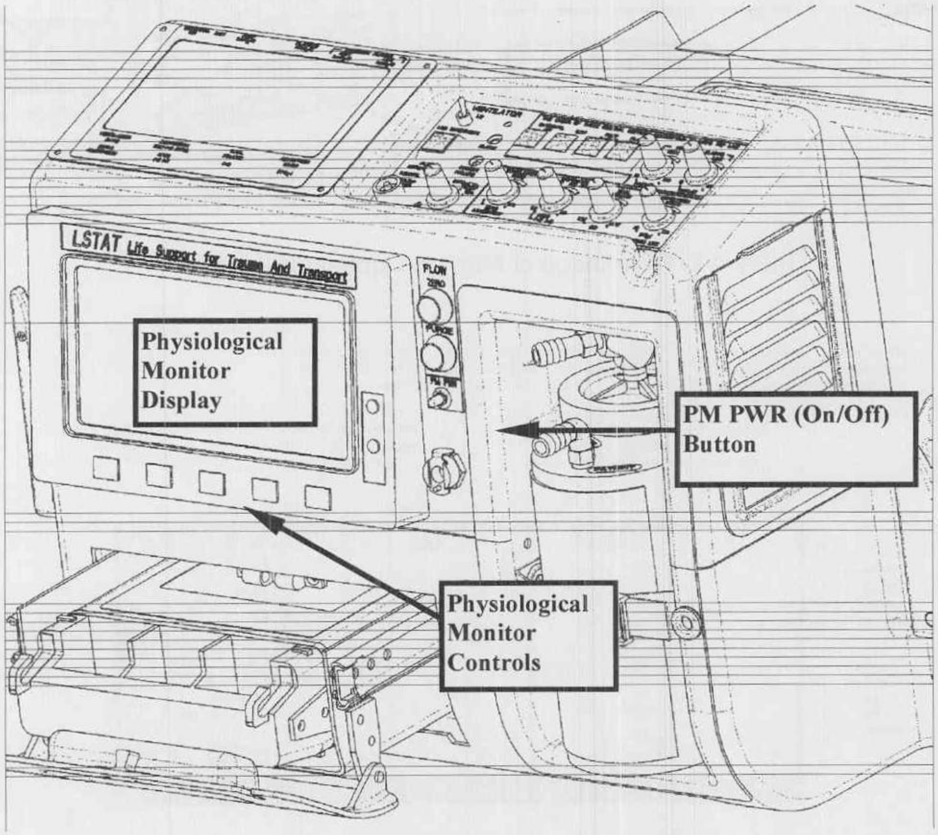

LSTAT Life Support for Trauma And Transport
VENTILATOR
FLOW ZERO
PURGE
PM PWR
Physiological Monitor Display
PM PWR (On/Off) Button
Physiological Monitor Controls

Figure 4-1. Physiological Monitor Controls and Display

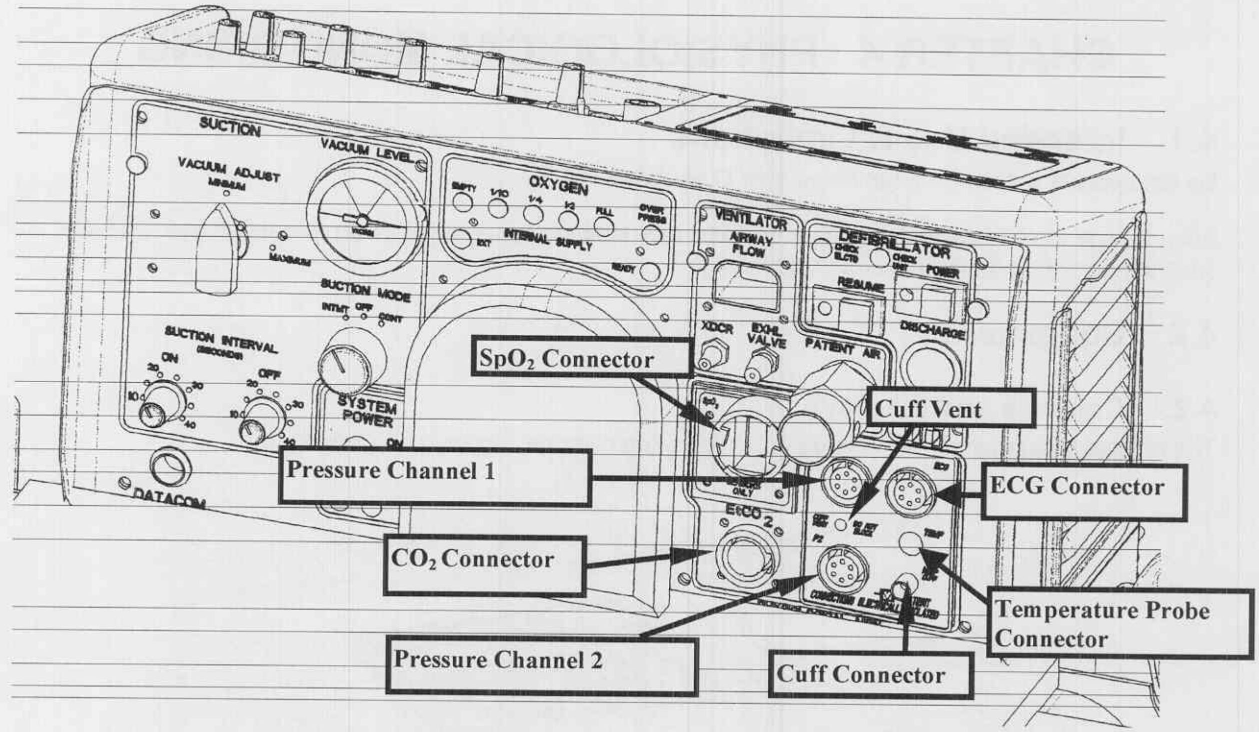
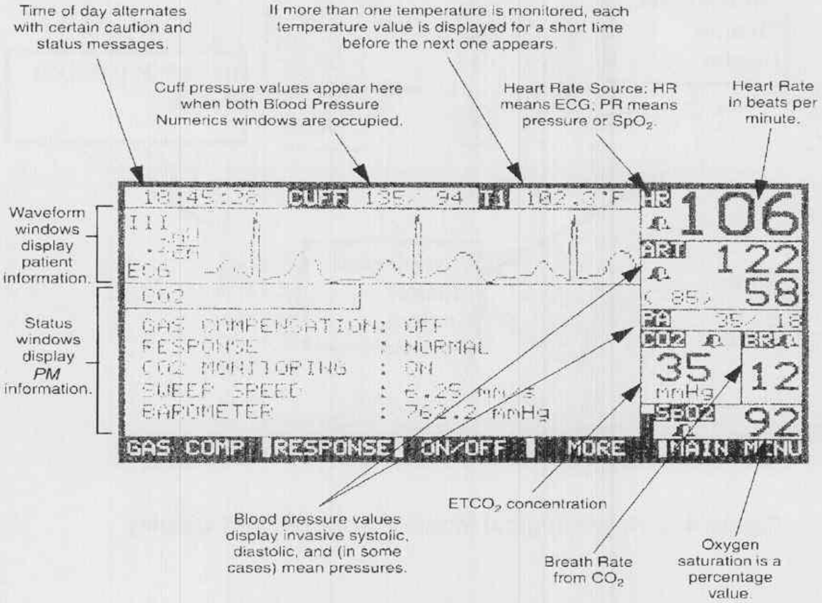

SpO$_2$ Connector
Cuff Vent
Pressure Channel 1
ECG Connector
CO$_2$ Connector
Temperature Probe Connector
Pressure Channel 2
Cuff Connector
SUCTION
VACUUM ADJUST
VACUUM LEVEL
OXYGEN
INTERNAL SUPPLY
VENTILATOR
AIRWAY FLOW
DEFIBRILLATOR
RESUME
POWER
DISCHARGE
SUCTION MODE
SUCTION INTERVAL
ON
OFF
SYSTEM POWER
XDCR
EXHL VALVE
PATIENT AIR
EtCO$_2$
DATACOM

Figure 4-2. Physiological Monitor Connector Panel


Time of day alternates with certain caution and status messages.
If more than one temperature is monitored, each temperature value is displayed for a short time before the next one appears.
Cuff pressure values appear here when both Blood Pressure Numerics windows are occupied.
Heart Rate Source: HR means ECG; PR means pressure or SpO$_2$.
Heart Rate in beats per minute.
Waveform windows display patient information.
Status windows display *PM* information.
18:45:26
CUFF 135/ 94
T1 102.3°F
HR 106
ART 122
(85) 58
PA 35/ 18
CO2 35 mmHg
BR 12
SPO2 92
III
ECG
CO2
GAS COMP
RESPONSE
ON/OFF
MORE
MAIN MENU
Blood pressure values display invasive systolic, diastolic, and (in some cases) mean pressures.
ETCO$_2$ concentration
Breath Rate from CO$_2$
Oxygen saturation is a percentage value.

```
GAS COMPENSATION: OFF
RESPONSE        : NORMAL
CO2 MONITORING  : ON
SWEEP SPEED     : 6.25 mm/s
BAROMETER       : 762.2 mmHg
```

This LCD display shows a fully-loaded PM monitoring all vital signs.

Figure 4-3. Physiological Monitor Vital Signs

4.3 Accessories

Use only the accessories provided or replaced per the accessory list. Use of other accessories may cause damage to the physiological monitor or indicate inaccurate patient information. Physiological monitoring accessories are listed in Appendix D under Physiological Monitor Subsystem Items.

4.4 Preparation for Use

4.4.1 Physiological Monitor Power

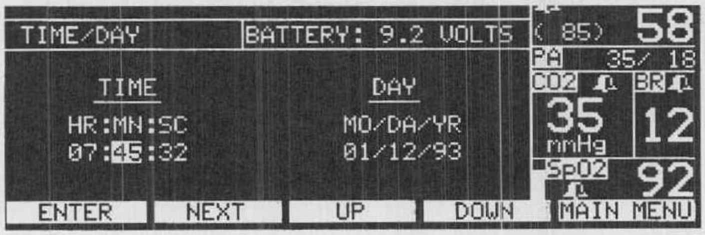
1. Make sure that the *SYSTEM POWER* switch is *ON.*
2. On the head fairing, press the *PM PWR* button to turn on the physiological monitor (Figure 4-1).
3. Observe the Main Menu is displayed in the physiological monitor display.

> NOTE
>
> The window will display start-up information while it performs a self-test.
>
> If an error is detected during start up, an error message window will appear.
>
> Refer to Table 4-15 for error handling.
>
> If information does not appear on the display, the contrast may be set too low. Adjust the display contrast. If the display still appears blank, press *PM PWR* to turn off the monitor, and press *PM PWR* to turn it back on. If the monitor screen remains dark, the physiological monitor may need servicing. Refer to Appendix E for servicing instructions.
>
> If any Menu option does not appear on the display, press the *MAIN MENU* button.

4.4.2 Setting the Time and Date

The time is shown in the upper left corner of the physiological monitor screen in twenty-four hour format. Make sure the time and date are set correctly before using the physiological monitor.

1. From the Main Menu, press *SYSTEM.*
2. Press *MORE.*
3. Press *TIME/DAY.* The Time/Day Menu will be displayed (Figure 4-4) with the cursor positioned for time adjustment.
4. Press the *NEXT* button to select the hours
5. Press the *UP* button to increase the value or the *DOWN* button to decrease the value.
6. Press *NEXT* to advance to minutes
7. Press *UP* or *Down* buttons for desired value.
8. Repeat the process to set the seconds, month, day, and year.
9. Press the *ENTER* button after the time and date are both set.
10. Press the *MAIN MENU* button to return to the Main Menu.
11. Set the default or the current setting, to retain time and day settings when physiological monitor power is turned off.



TIME/DAY BATTERY: 9.2 VOLTS

TIME
HR:MN:SC
07:45:32

DAY
MO/DA/YR
01/12/93

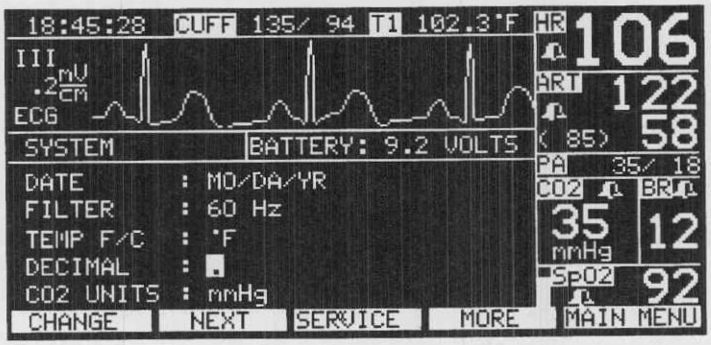
Figure 4-4. Time/Day Menu

4.4.3 Changing System Settings.

The physiological monitor provides the capability to customize the system functions listed in Table 4-1. The settings are shown in the System Status Screen (Figure 4-5).

Table 4-1. System Settings

Function	Description and Settings
DATE	Sets the date format: Month/Day/Year or Day/Month/ Year
FILTER	Sets the ECG filter frequency. Usually set to the ac mains frequency: 60 Hz for North America; 50 Hz for most European and South American countries. Parts of Japan use 50 Hz, others use 60 Hz.
TEMP F/C	Sets the temperature display units: Fahrenheit or Celsius.
DECIMAL	Sets the decimal character as either a period (.) or a comma (,).
CO_2 UNITS	Sets the CO2 display units as mmHg, kPa, or percent (%).



SYSTEM
BATTERY: 9.2 VOLTS
DATE : MO/DA/YR
FILTER : 60 Hz
TEMP F/C : °F
DECIMAL : .
CO2 UNITS : mmHg

Figure 4-5. System Status

1. From the Main Menu, press the *SYSTEM* button.
2. Press *MORE*.
3. Press *MORE* again.
4. Press *CHANGE* to toggle the setting to the desired format.
5. Press *NEXT* to advance to the next setting.
6. Press *MAIN MENU* to return to the Main Menu.

4.4.4 Changing Power-On Settings

The physiological monitor is delivered with factory defaults (Table 4-12). The display contrast, alarm limit values, trend graph scales, and all patient monitoring parameters can be set for your particular application.

For each setting, from the Main Menu press *System* and then press *Program*.

Adjust Display Contrast:

1. Press *DISPLAY*.
2. Press *CONTRAST*. Contrast becomes lower each time *CONTRAST* is pressed until reaching the lowest setting. If contrast is at the lowest setting, pressing *CONTRAST* returns the display to its highest setting.
3. Press *MAIN MENU*.

To Set Alarm Volume And Other Display Parameters:

1. Press *DISPLAY*.
2. Press *MORE*.
3. Press *CHANGE* to change each display parameter (alarm tone volume, heart tone volume and heart rate source)
4. Press *NEXT* to advance to the next parameter.
5. Press *MAIN MENU*.

To Set Alarm Limits.

1. Press *ALARMS*.
2. Set each alarm limit value.

NOTE

The alarm for apnea cannot be turned off at any time.

If you change the patient mode, the alarm limit settings are automatically changed to the defaults for that mode.

WARNING

IF ANY ALARMS ARE SET TO *OFF* AND YOU SELECT *CURRENT* TO SET THE CURRENT SETTINGS AS POWER-ON SETTINGS, THOSE ALARMS WILL BE OFF AT POWER- ON FOR SUBSEQUENT *PATIENTS. CONSIDER CAREFULLY BEFORE SETTING POWER-ON ALARMS TO OFF.*

To Change ECG Settings:

1. Press *SENSORS*.
2. Press *ECG*.
3. Set each ECG parameter, as desired (*ECG LEAD*, *ECG SIZE*, *HR/PR TONE* and *PACER*).
4. Press *MAIN MENU*.

To Change Invasive Pressure Settings:

1. Press *SENSORS*.
2. Press *INV PRS*.
3. Press *RANGE* to set the desired invasive pressure range.
4. Press *MAIN MENU*.

To Change Cuff Settings:

1. Press *SENSORS*.
2. Press *CUFF*.
3. Press *AUTO* to have the cuff ready to automatically take blood pressure measurements when *PM PWR* is turned on. Otherwise press *MANUAL*.
4. If *AUTO* was selected, press *INTERVAL* until the desired measurement interval is displayed next to the word TIME.
5. Press *MAIN MENU*.

To Change Spo$_2$ Settings:

1. Press *SENSORS*
2. Press *SpO$_2$*.
3. Set each SpO$_2$ parameter, as desired (*SIZE*, *C-LOCK*, and *RESPONSE*).
4. Press *MAIN MENU*.

To Change CO2 Settings:

1. Press *SENSORS*.
2. Press *MORE*.
3. Press *CO$_2$*.
4. Set each CO$_2$ parameter, as desired (*RANGE*, *mm/sec*, *GAS COMP*, *RESPONSE* and *ON/OFF*).
5. Press *MAIN MENU*.

To Change Trend Graph Settings:

1. Press *DISPLAY*.
2. Press *TREND*.
3. Press *RESCALE* to set the scale of each trend the first time it is displayed.
4. Press *NXT PAGE* to select the next trend to scale.

5. After all trend graph scales are set, press *NXT PAGE* to select the trend you want to appear the first time you press the *TREND* button during operation.
6. Press MAIN MENU.

> NOTE
>
> After changing the settings, they become the current settings. To retain these settings when the physiological monitor is turned off, the settings must be programmed as power-on settings.

To Set Current Settings As Power-On Settings:

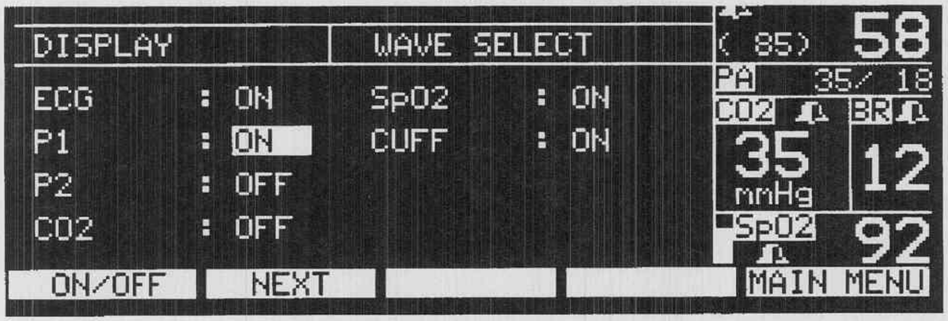
1. Press *SYSTEM*.
2. Press *MORE*.
3. Press *PROGRAM*.
4. Press *CURRENT*.
5. Press *MAIN MENU*.

To Return To Default Settings:

1. Press *SYSTEM*.
2. Press *MORE*.
3. Press *PROGRAM*.
4. Press *DEFAULT*.
5. Press *MAIN MENU*.

4.4.5 Selecting Waveforms

The physiological monitor can monitor up to six vital signs. It can display up to three waveforms at any time. The last NIBP cuff measurement can be displayed in place of the waveforms.



ECG : ON
P1 : ON
P2 : OFF
CO2 : OFF
SpO2 : ON
CUFF : ON

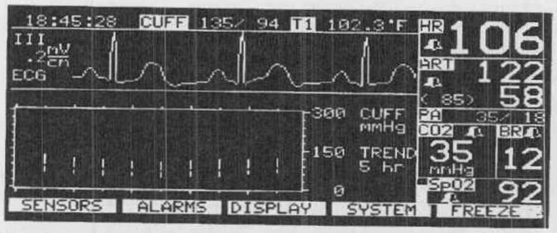
Figure 4-6. Wave Select Screen

> NOTE
>
> Because of the critical nature of the ECG waveform, ECG cannot be turned *OFF*. If ECG is not monitored, another waveform will occupy its place.
>
> More than three waveforms can be *ON*, but only the first three waveforms in the window will be displayed.

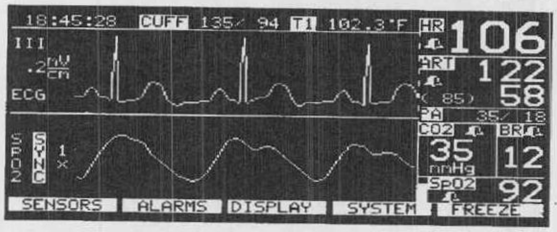
To select the waveforms, perform the following from the Main Menu:

1. Press *DISPLAY*.
2. Press *MORE*.
3. Press *WAVE SEL*.
4. In the Wave Select Screen (Figure 4-6), press the button corresponding to *ON/OFF* to set the desired waveform.
5. Press *NEXT* to advance to the next vital sign.

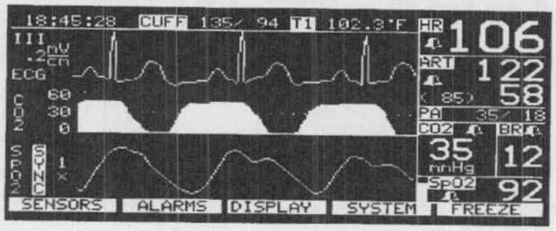
6. When finished, press *MAIN MENU* to return to the Main Menu Screen.


18:45:28
CUFF 135/ 94
T1 102.3°F
HR 106
ART 122
(85) 58
III
.2 mV/cm
ECG
300 CUFF mmHg
150 TREND 5 hr
0
PA 35/ 18
CO2 35 mmHg
BR 12
SpO2 92
SENSORS
ALARMS
DISPLAY
SYSTEM
FREEZE

A single waveform above a trend is displayed by turning on only the desired waveform in the wave select window. If ECG is monitored it will automatically be selected for display. (ECG cannot be turned off.) If ECG is not monitored, the selected waveform will be shown.


18:45:28
CUFF 135/ 94
T1 102.3°F
HR 106
ART 122
(85) 58
III
.2 mV/cm
ECG
SPO2
SYNC
1 x
PA 35/ 18
CO2 35 mmHg
BR 12
SpO2 92
SENSORS
ALARMS
DISPLAY
SYSTEM
FREEZE

Two waveforms are displayed by turning on only one other waveform if ECG is monitored. If ECG is not monitored, turn on the two desired waveforms.


18:45:28
CUFF 135/ 94
T1 102.3°F
HR 106
ART 122
(85) 58
III
.2 mV/cm
ECG
CO2
60
30
0
SPO2
SYNC
1 x
PA 35/ 18
CO2 35 mmHg
BR 12
SpO2 92
SENSORS
ALARMS
DISPLAY
SYSTEM
FREEZE

Three waveforms are displayed by turning on three or more waveforms. Only the first three in the list that are turned on will be displayed.

Figure 4-7. Example Waveform Displays.

4.4.6 Transitioning Patients

To transition between patients using the physiological monitor:

1. Press the *PM PWR* button to turn OFF the monitor.
2. Wait a few seconds. This clears the prior patients trend values, alarm limit settings and non-invasive blood pressure (NIBP) cuff inflation target.
3. Press the *PM PWR* button to turn ON the monitor.

4.5 Electro-Cardiogram (ECG)

4.5.1 Intended Use

The physiological monitor is intended for ECG monitoring of leads I, II, III and Margot Configuration 1 (MCL1). MCL1 requires all three electrodes.

The physiological monitor is not intended for *diagnostic* ECG monitoring.
The physiological monitor may be used on patients with pacemakers. However, as with many monitoring devices, pacemaker patients should be kept under close or constant observation. The Association for Advancement of Medical Instrumentation (USA) cautions that "in some devices, rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmia's. DO NOT RELY ENTIRELY UPON THE RATE METER ALARMS. Keep pacemaker patients under close observation."

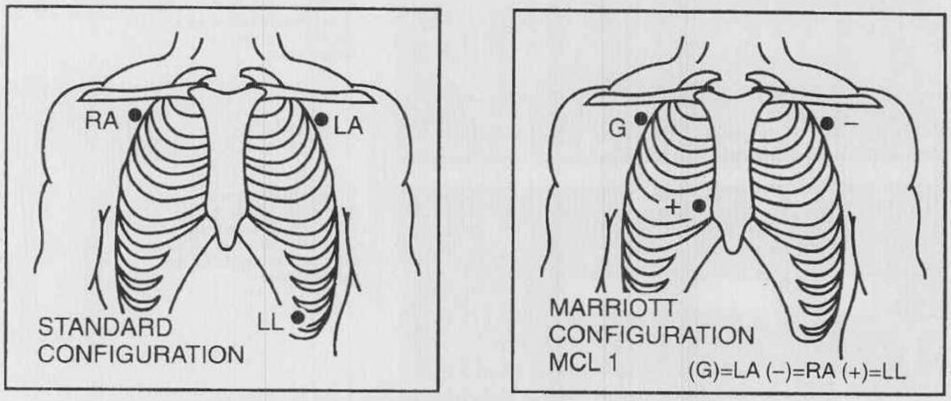
4.5.2 ECG Preparation

1. Take the ECG cable and ECG electrodes from the accessory bag.
2. Inspect the ECG cable for wear, breakage, or fraying. Replace if the cable shows any signs of damage.
3. Connect the ECG cable into the ECG connector on the Physiological Monitor Panel located on the Operator/Patient Interface Panel (Figure 4-2).
4. Support the ECG cable so it does not stress the electrode wires, electrode wire/ECG cable connectors, or electrodes.

5. If an ELECTROSURGICAL unit is going to be used, place the ECG cable and electrode wires so that interference will be minimal.

4.5.3 ECG Leads Placement

1. Thoroughly clean the skin areas where the electrodes will be attached.
2. Attach the lead wires to the electrodes before applying them to the patient.
3. Apply the electrodes to the patient in either the standard lead configuration or the Marriott configuration for Modified Chest Lead (MCL1) monitoring, as shown in Figure 4-8.
4. If using MCL1, select LEAD II on the physiological monitor and use all three electrodes.



Placing ECG leads for the standard or Marriott configuration.

Figure 4-8. ECG Leads Placement

NOTE

If pre-gelled electrodes are used, use only those electrodes that are not expired.

Make sure there is a generous amount of gel in the electrode and that it has not dried. For best results, use silver/silver chloride electrodes.

If non-gelled electrodes are used, apply a 1/4 to 1/2-inch mound of gel over the electrode contact area.

Some electrodes may be subject to large offset potentials due to polarization. This effect is most likely when dissimilar metals are used for different electrodes, and may be severe enough to prevent obtaining an ECG trace. Furthermore, recovery time after application of defibrillation pulses may be compromised when using electrodes of dissimilar metals. Squeeze bulb electrodes, even if all of the same metal, are particularly vulnerable to this effect. Stainless steel needle electrodes are prone to having large erratic offset drifts and are not recommended.

4.5.4 ECG Waveform and Filtering

After correct placement of the ECG leads, the ECG waveform will be displayed (e.g., Figure 4-9). The waveform will be centered in the display area and sweep from left to right. The waveform may exhibit noise or pacer indications (dashed vertical lines).

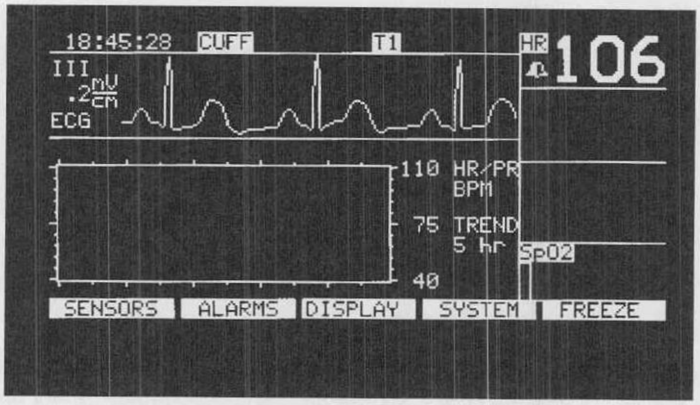
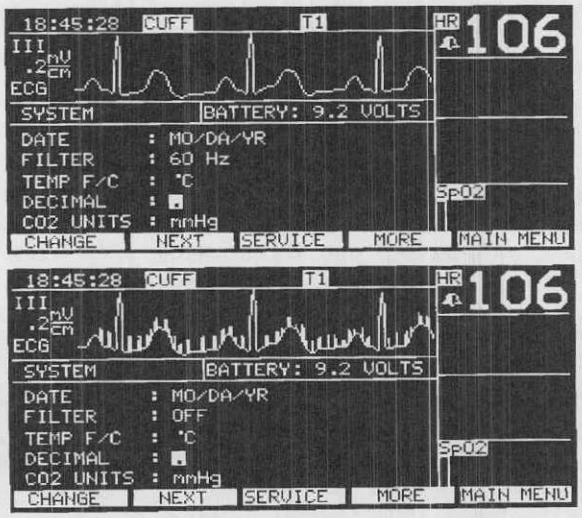

18:45:28
CUFF
T1
HR
106
III
.2 mV/cm
ECG
110 HR/PR BPM
75 TREND 5 hr
40
SpO2
SENSORS
ALARMS
DISPLAY
SYSTEM
FREEZE

Figure 4-9. ECG Waveform and Display

If the ECG waveform is exhibiting noise it may be desirable to activate the ac mains filter by performing the following steps from the Main Menu:

1. Press *SYSTEM*.
2. Press *MORE*.
3. Press *MORE* again.
4. Press *NEXT* to select the FILTER.
5. Press *CHANGE*. This will turn the filter OFF and mains noise may show up on the display.
6. Press *CHANGE* again. This will turn the filter ON and reduce noise. Figure 4-10 shows an example of filtered and unfiltered waveforms.


18:45:28
CUFF
T1
HR
106
III
.2 mV/cm
ECG
SpO2
CHANGE
NEXT
SERVICE
MORE
MAIN MENU

SYSTEM BATTERY: 9.2 VOLTS
DATE : MO/DA/YR
FILTER : 60 Hz
TEMP F/C : °C
DECIMAL : ■
CO2 UNITS : mmHg

SYSTEM BATTERY: 9.2 VOLTS
DATE : MO/DA/YR
FILTER : OFF
TEMP F/C : °C
DECIMAL : ■
CO2 UNITS : mmHg

Differences in ECG waveform with filter on and set to 60 Hz (top) and off (bottom)

Figure 4-10. Waveform Filter

4.5.5 HR/PR Tone

Heart rate is displayed to the right of the ECG waveform (Figure 4-9). An HR/PR tone beeps for each QRS event or, if the heart rate source is a pressure channel or SpO_2, for each detection of a pulse wave. The HR/PR tone volume can be set LOW, MEDIUM, or HIGH or turned off using the *HR/PR TONE* button. The HR/PR tone can be set in both the ECG and Display status windows.

NOTE

The QRS detector sensitivity threshold is not affected by changing the ECG display size.

If SpO_2 is monitored, the heart tone is produced by the speaker in the SpO_2 option. The pitch of the tone varies with the SpO_2 value. If SpO_2 is not monitored, the heart tone is produced by the speaker in the physiological monitor.

The mm/sec setting of a CO_2 display (not synchronized with the heart) is set independently.

4.5.6 PACER Function

If the patient being monitored has a pacemaker, the physiological monitor detects indicates the occurrence of pacemaker signals. Pacemaker signals are not counted as heart beats as long as the pacemaker signal meets the pulse amplitude, pulse width, and overshoot/undershoot specifications for Pacer Pulse Rejection:

Pacer will not count approximately 95% of pacemaker pulses of 0.1 to 2 ms duration, ± 2 mV to ± 700mV, with or without AAMI (EC13 1983) tails for all decay time constants (TC). Tails are 2.5%, maximum 2 mV, TC = 25, 50, 75, 100 ms.

Pacer detection range (i.e. will show the dashed vertical marker) for 0.1 ms pulses is ± 3 mV to 700 mV, and drops linearly to ± mV to 700 mV for 0.2 to 2 ms pulses.

WARNING

PACEMAKER SIGNALS CAN DIFFER FROM ONE PACEMAKER TO THE NEXT. THE ASSOCIATION FOR ADVANCEMENT OF MEDICAL INSTRUMENTATION (USA) CAUTIONS *THAT "IN SOME DEVICES. RATE METERS MAY CONTINUE TO COUNT THE PACEMAKER RATE*

To Turn the PACER function ON or OFF

1. Press the *PACER* button on the ECG Menu.

PACER status is displayed in the ECG window above the menu (Figure 4-11). Vertical dashed lines will be displayed each time a pacemaker signal is detected when the *PACER* function is ON. The pacer "spike" is also displayed. Whether the pacer is atrial, ventricular or both, the indicator and the spike are displayed. If the *PACER* function is turned OFF, only the pacemaker spike is displayed.

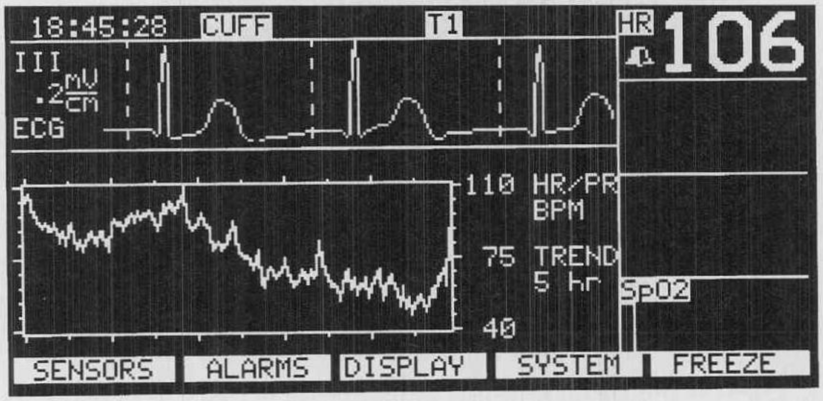


Figure 4-11. Pacer Indicator

4.5.7 ECG Removal

1. Remove and discard the ECG electrodes when no longer required.
2. Clean the ECG cables per the instructions in Section 12.2.2.

4.6 Invasive Pressure

The invasive pressure channel measures arterial pressure, pulmonary artery pressure, central venous pressure and intracranial pressures. The invasive pressure range is from -30 to 300 mmHg.

The standard invasive pressure connector is a 6-pin connector, compatible with the ITT®-Cannon ® connect MS3106F-14S-6P. The invasive pressure channels require transducers with 5µV/V/ mmHg sensitivity. The physiological monitor can be used with many types of transducers, including non-disposable, disposable dome, and fully disposable. Recommended transducers are listed in Table 4-2.

Table 4-2. Recommended Invasive Pressure Transducers

Manufacturer	Transducer	Cable #
Abbot Critical Care Salt Lake City, UT (800) 222-6883 (708) 937-1760	Disposable Tanspac II Disposable Transpac III	42574-04-04 42661-04-27
Concord-Porter (Telos) Keene, NH (800) 258-5361 (603) 352-3812	Reusable R0001 Disposable T6000 Disposable T6003	R1014 T65-1014 T65-1014
COBE Laboratories, Inc. Lakewood, CO (800) 525-2623 (303) 232-6800	Disposable CDXIII Disposable CDXpress	041-709-012 041-709-012
Utah Medical Products, Inc. Midvale, UT (800) 533-4984 (801) 566-1200	Disposable Deltran II 6199 (non-sterile) DPT-200 (sterile)	650-208
Viggo-Spectramed, Inc. Oxnard, CA (800) 235-5945 (805) 983-1300	Disposable DTX, DTX+	TC-VTK
Medex, Inc. Hilliard, OH (800) 848-1757 876-2413	Disposable MX900 MX9504CSTT MX4805	MX900-42 MX98014
Baxter Healthcare Edwards Division Santa Ana, CA (800) 424-3278 (714) 250-2500	Trantec Disposable 53 Series Disposable 43 Series Disposable 33 Series	892083002 893206001 895083001

NOTE
The HP1290C option J01 transducer is not compatible with the standard physiological monitor even though it can physically connect into the physiological monitor's on the patient interface panel. Use a compatible transducer.

4.6.1 Connecting the Invasive Pressure Cable

1. Take the transducer cable and invasive BP transducer set from the accessory bag (or obtain from a recommended manufacturer).
2. Inspect the transducer cable for wear, breakage, or fraying. Replace the cable if any of these are visible. Replace the transducer dome if necessary.
3. If the transducer is a disposable unit with a separate cable, connect the transducer to the transducer cable.
4. Connect the transducer cable into the invasive pressure connector labeled P1 or P2 on the physiological monitor connector panel (Figure 4-2).
5. Depending on the zone, observe the message NOT ZEROED or NO ZERO in the blood pressure numerics window for the invasive pressure channel being used.
6. Zero the transducer.

WARNING

ALWAYS AVOID USING ANY TRANSDUCER WITH A CONDUCTIVE (METAL) CASE THAT IS ELECTRICALLY CONNECTED TO THE CABLE SHIELD. USING A CONDUCTIVE TRANSDUCER CASE WITH SUCH A SHIELD CONNECTION INCREASES SHOCK HAZARDS BECAUSE IT DEFEATS THE PATIENT ISOLATION BARRIER. USE OF A TRANSDUCER WITH A CONDUCTIVE CASE ALSO INCREASES THE RISK OF BURNS DURING ELECTROCAUTERY PROCEDURES.

4.6.2 Zeroing the Transducer

1. Open the transducer stopcock to atmospheric air.
2. Wait a few seconds for the transducer to settle.
3. If the ZERO label does not appear on the display:
4. Press *SENSORS*.
5. Press *INV PRS*.
6. Press *MORE.*
7. Press *ZERO P1* or *ZERO P2*, depending on the pressure channel being monitored
8. Observe the word *ZEROING* appears in the numerics window during zeroing.

During zeroing, *ZERO P1* (or *ZERO P2*) changes to *CANCEL* to allow cancellation of the zeroing process, if necessary. Zeroing messages appear in the blood pressure numerics window. If the zero value is accepted, the word ZEROED appears in the blood pressure numerics window for a few seconds. The monitor then displays the pressure scale to the left of the waveform, and the pressure numerics appear.

9. Wait for a tone to briefly sound and the word ZEROED to appear in the blood pressure numerics window.
10. If ZERO REJECTED or NO ZERO is displayed, press *CANCEL* and attempt to zero again. If the transducer still does not zero, attempt the same procedure with another transducer or another cable.
11. Observe the pressure scale appears next to the waveform.
12. Close the transducer's stopcock.

CAUTION

If the ZERO button (*ZERO P1 or ZERO P2*) is pressed after an invasive pressure channel has been successfully zeroed and is currently monitoring a pressure waveform, the message ZERO REJECTED will display in the invasive pressure numerics window. This message will preempt the valid invasive pressure numerics that were displayed in this zone prior to the unintentional *ZERO* button press and will continue to preempt the numerics until *CANCEL* is pressed. In addition, if the invasive pressure channel enters an alarm condition while the ZERO REJECTED message is overriding the invasive pressure numerics, no invasive pressure numerics will flash between inverse and normal to identify which patient channel is in alarm.

4.6.3 Setting Invasive Pressure Channel Functions

1. Press *SENSORS*.
2. Press *INV PRS*.
3. Press *RANGE*, or *RESCALE* to set, as desired.
4. Press *MORE.*
5. Press *LABEL*, or *FORMAT* to set, as desired.
6. Set Alarm limits.

4.6.4 Invasive Pressure Removal

1. Remove and discard the Invasive BP transducer set when no longer required.
2. Clean the IPB cable per the instructions in Section 12.2.2.

4.7 Non-invasive Blood Pressure Channel (NIBP or Cuff)

The non-invasive blood pressure channel (NIBP or cuff) measures arterial pressures using an inflatable cuff. If ECG is also monitored, the physiological monitor synchronizes the cuff measurement process to the occurrences of the R-wave, increasing accuracy in cases of extreme artifact.

Although it is not necessary for accurate cuff measurements, it is recommended that the ECG be monitored when the cuff is used on patients exhibiting high artifact, diminished pulses, or some dysrhythmias.

4.7.1 Intended Use

The NIBP is intended for use only on pediatric and adult patients with a limb circumference of at least 18 cm for the limb on which the cuff is to be placed. It is not intended for use on neonate patients or any patient with a limb circumference less than 18 cm.

Blood pressure measurements determined with the physiological monitor are equivalent to those obtained by a trained observer using the cuff, stethoscope auscultation method, within the limits prescribed by the American National Standard for Electronic or Automated Sphygmomanometers (United States of America).

The physiological monitor uses the oscillometric method to determine blood pressure. Oscillometry directly detects mean arterial pressure values by (1) occluding a limb artery in stages and (2) monitoring small changes in the cuff's pressure caused by blood pulsing against the cuff pressure. The systolic and diastolic pressures are calculated from the mean pressure based on a patented, proprietary calculation determined by extensive research.

As with any manual or automatic auscultatory or oscillometric pressure measurement technique, the following can adversely affect measurement determination:

Patients exhibiting cardiac arrhythmias, sudden changes blood pressure, convulsions, shivering, or other body motion

Hospital personnel or other non-stationary objects in contact with the cuff (changes in pressure caused by an object bumping against the cuff can result in erroneous or abortive readings)

When Auscultation is used to verify diastolic pressures, use the fifth phase of the Korotkoff sounds (that is, the point when the sound is no longer audible).

WARNING

NEVER MONITOR NIBP ON ONE PATIENT WHILE SIMULTANEOUSLY MONITORING ECG ON ANOTHER PATIENT.

CUFF PRESSURE LEVELS AND INFLATION RATES COULD INJUR NEONATES. DO NOT USE ON NEONATES.

IF A NIBP MEASUREMENT IS SUSPECT, REPEAT THE MEASUREMENT. IF THERE IS STILL UNCERTAINTY ABOUT THE READING, USE ANOTHER METHOD.

DO NOT ATTEMPT TO TAKE CUFF PRESSURES ON PATIENTS DURING CARDIOPULMONARY BYPASS.

DO NOT USE IN A MAGNETIC RESONANCE IMAGING (MRI) ENVIRONMENT. THE MAGNETIC FIELD CAN DAMAGE THE NIBP PUMP AND INDUCE POTENTIALLY HARMFUL CURRENTS IN ANY MOVING LEAD WIRES.

4.7.2 Cuff Placement and Connection

The physiological monitor uses a single-hose cuff available in various sizes. The cuff is easily connected and disconnected from a screw-on connector (Figure 4-2). The cuff vent allows air to be pumped into the cuff during inflation and vented to the room during deflation. The vent should always remain free from obstructions.

1. Obtain an appropriate NIBP Cuff.
2. Squeeze as much air from the cuff as possible.
3. Place the cuff on the patient.
4. Screw the hose connector, finger tight, onto the cuff connector.

4.7.3 Setting the Cuff Channel

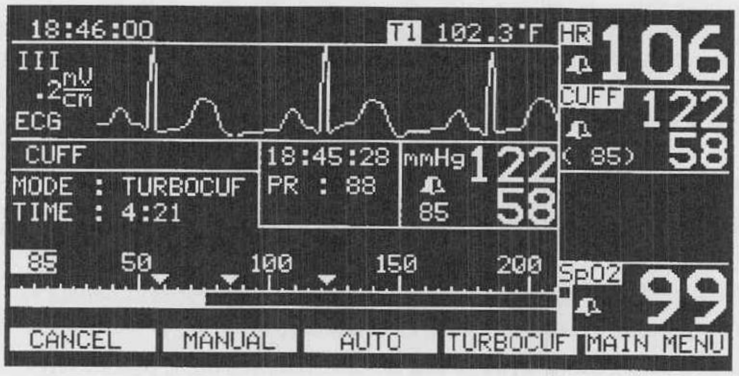
The physiological monitor can be set to take measurements manually (MANUAL), automatically at periodic intervals from one minute to 60 minutes (AUTO), or consecutively for a period of five minutes (TURBOCUF). Table 4-3 lists the Cuff menu buttons and their functions. Figure 4-12 shows the cuff status window and the Cuff Menu.

1. Press *SENSORS*.
2. Press *CUFF*.
3. Press *MANUAL*, *AUTO/INTERVAL*, or *TURBOCUF* to set cuff function.
4. Press *START*.

Typical cuff measurements are completed within 30 seconds. If the physiological monitor cannot take a valid cuff measurement within two minutes (longer when using the thigh cuff to allow ample time for inflation), it automatically deflates. However, as with any measurement device that impairs circulation, the patient's limb should be periodically observed to ensure that the circulation is not impaired for a prolonged period of time. The cuff automatically deflates if cuff pressure exceeds 260 mmHg for any reason. A safety valve exists in the system to ensure that cuff pressure never exceeds 330 mmHg, even if the normal deflation valve fails.

Table 4-3. Cuff Menu Functions

Button	Function
START/ CANCEL	Starts a blood pressure measurement, whether or not the physiological monitor is set to automatically take measurements. When START is pressed, the button label changes to CANCEL in order to cancel the measurement, if necessary.
MANUAL	Turns off automatic interval measurements. The INTERVAL label changes to AUTO.
AUTO/INTERVAL	Sets the physiological monitor to automatically initiate a noninvasive pressure measurement at intervals from one minute to 60 minutes. When AUTO is pressed the button changes to INTERVAL, and the first interval is shown on the display next to the word "TIME". Press the INTERVAL button to change the interval until the desired value is displayed. Any time the physiological monitor is taking a noninvasive pressure measurement, the START button changes to Cancel so the measurement can be stopped in progress.
TURBOCUF	Automatically begins taking consecutive noninvasive pressure measurements for five minutes. As soon as one measurement is complete, the next one starts. After five minutes, measurements are stopped. Any measurement can be canceled by pressing the CANCEL button.



MODE : TURBOCUF
TIME : 4:21
PR : 88

The cuff status window shows the current cuff pressure on the manometer bar, the last measurement, the time and pulse rate of the last measurement, and the measurement mode.

Figure 4-12. Cuff Status Window

Automatic Measurements

When the selected interval is from 5 to 60 minutes, a blood pressure measurement will begin when the minute of the time of day clock is evenly divisible by the interval. For example, if the interval is set to 10 (minutes) measurements will begin at the hour and at 10, 20, 30, 40, and 50 minutes past the hour.

When the selected interval is from 1 to 3 minutes, the monitor waits the selected time between the beginning of each measurement. The results may vary if the measurement takes longer than 30 seconds, because the monitor requires that the cuff pressure be below 5 mmHg for a minimum of 30 seconds between measurements to give the patient's arm a chance to restore blood flow to the limb. If on AUTO INTERVAL, one additional reading will be taken immediately after an auto reading that results in a patient alarm.

Cuff measurements can always be started manually by pressing the *START* button, even if the physiological monitor is set to automatically take cuff measurements. A new measurement will be automatically initiated if the physiological monitor is set to AUTOINTERVAL and a manual or automatic measurement results in a patient alarm.

4.7.4 Cuff Removal

1. Remove cuff.
2. Clean the reusable Non-Invasive BP Cuff and hose per the instructions contained in Section 12.2.2.

4.8 Temperature

The physiological monitor provides one temperature channel. °C or °F units may be selected for the temperature.

WARNING

A METAL-JACKETED TEMPERATURE PROBE THAT CONTACTS CONDUCTIVE OBJECTS DURING ELECTROCAUTERY MAY INCREASE THE POSSIBILITY OF RF BURNS AT THE TEMPERATURE PROBE SITE OR AT THE ECG ELECTRODES, ESPECIALLY IF THE OBJECT THE PROBE CONTACTS IS EARTH GROUNDED. DURING APPLICATION OF THE PROBE, BE SURE THAT IT IS NOT ALLOWED TO TOUCH CONDUCTIVE OBJECTS. DURING ELECTROCAUTERY BE SURE THAT THE PROBE DOES NOT CONTACT CONDUCTIVE OBJECTS AND IS NOT IN CONTACT WITH CLINICAL PERSONNEL.

Use only Yellow Springs instrument (YSI) Company's Models 400 and 700 Series temperature probes or equivalent. Temperature probes that do not match the performance specifications of these probes may produce incorrect temperature readings. Several different types of probes can be used, including esophageal, rectal, needle, and skin.

4.8.1 Temperature Placement and Connection

1. Take the temperature sensor cable, temperature sensor and an appropriate temperature probe from the accessory bag.
2. Place the probe on the patient. (Use the Heart shaped "stick-ons" for skin sensors)
3. Connect the probe into the Temperature Probe connector (Figure 4-2).
4. Observe the temperature value displayed to the left of the heart rate (Figure 4-13).

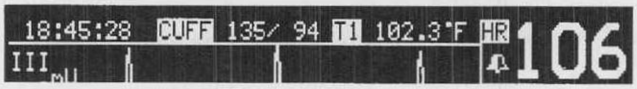


Figure 4-13. Temperature Numeric

4.8.2 Temperature Settings

To select the temperature units, from the Main Menu:

1. Press *SYSTEM.*
2. Press *MORE.*
3. Press *MORE* again.
4. Press *NEXT* twice to select temperature.
5. Press *CHANGE* to toggle the temperature units between Celsius and Fahrenheit.
6. Press *MAIN MENU* to return to the main menu screen.
7. Observe the temperature displays the newly selected units.
8. Set the Alarm limits according to organizational procedures.

4.8.3 Temperature Probe Removal

1. Discard the disposable Temp Sensors, Probes and Temp Heart Stick-Ons when no longer required.
2. Clean the reusable Temp sensor Cable per the instructions contained in CHAPTER 12, paragraph 12.2.2

4.9 SpO$_2$

The pulse oximetry (SpO$_2$) patient channel non-invasively measures oxygen saturation of arteriolar hemoglobin at a peripheral measurement site, such as a finger, toe, or the bridge of the nose. SpO$_2$ is the most recent standard term assigned to measuring oxygen saturation using a pulse oximeter as opposed to an arterial blood sample (SaO$_2$).

4.9.1 Intended Use

The SpO$_2$ option is intended for use only as an adjunct in patient assessment. The SpO$_2$ option must be used in conjunction with patient signs and symptoms. Oxygen saturation measurements using pulse oximetry are highly dependent on proper placement of the sensor and patient conditions. Conditions such as shivering may cause artifact, resulting in erroneous oxygen saturation readings. Patient conditions, such as smoke inhalation, can cause SpO$_2$ measurements to be suspect. If pulse oximetry measurements are suspect, verify the reading using another clinically accepted measurement method, such as arterial blood gas measurements.

The SpO$_2$ option has been designed to match the performance of a NELLCOR N-200 Pulse Oximeter. The SpO$_2$ option is intended for use on adult and pediatric patients using only NELLCOR oxygen transducers (sensors). It is not intended for use on neonatal patients.

Only NELLCOR oxygen transducers, including OXISENSOR patient dedicated adhesive sensors, should be used. See Table 4-4 for a list of compatible sensors.

The SpO_2 channel is self-calibrating, assuring accurate measurements. Self-calibration is performed when the monitor is first turned on, at least every 15 minutes thereafter (sometimes sooner if the channel detects it is needed), and whenever a sensor is connected to the channel.

4.9.2 Oxygen Saturation and Heart Tone

One of the most unique aspects of SpO_2 is the audible heart tone indicating changes in the measured oxygen saturation level. When SpO_2 is being measured, the heart tone is produced using a special speaker in the LSTAT. As the oxygen saturation increases or decreases, the pitch of the heart tone rises and falls. This provides immediate recognition of saturation changes. If SpO_2 is not being monitored, the heart tone is produced by the physiological monitor speaker.

4.9.3 Measurement Range

The measurable range of saturation depends on the sensor used for measurement, but SpO_2 can display from 0 to 100 percent saturation on both adult and pediatric patients.

4.9.4 SpO_2 Sensors and Connection

The NELLCOR oxygen sensor or a sensor extender cable, such as the 8-foot extension cable, can be directly connected to the D-type connector (Figure 4-2).

SpO_2 has been designed to operate with a wide range of NELLCOR, INC. oxygen transducers. Table 4-4 lists the NELLCOR accessories and sensors that may be used. These sensors have no heat source to burn a patient, and NELLCOR sensors are accurately calibrated at the factory.

Table 4-4. NELLCOR SpO_2 Sensors

Mode	Description*
DS-100A	DURASENSOR ® Adult Digit Oxygen Transducer
D-25	OXISENSOR™ Adult Digit Oxygen transducer (18" cable)
D-25L	OXISENSOR ™ Adult Digit Oxygen Transducer (36" cable)
D-20	OXISENSOR™ Pediatric Digit Oxygen Transducer
R-15	OXISENSOR™ Adult Nasal Oxygen Transducer
EC-4	NELLCOR Sensor Extension Cable (4ft)
RS-10	Reflectance Oxygen Transducer
DF-A	DURAFORM™ Oxygen Transducer System

*NELLCOR's DURASENSOR® is a reusable oxygen transducer supplied in a non-sterile package. Its optical components are mounted in a plastic casing. OXISENSOR™ oxygen transducers are sterile adhesive sensors. Their optical components are mounted in medical-grade adhesive tape.

NOTE

Each sensor is designed to apply to a specific site on a patient within a certain size range. To select the appropriate sensor, consider the patient's weight and which sensor application sites are available, as well as the adequacy of the patient's perfusion, the level of patient activity, whether sterility is required, and the anticipated duration of monitoring.

If poor patient perfusion affects instrument performance and the patient weighs more than 50 kg, consider using the OXISENSOR R-15 adult nasal oxygen transducer. Since the R-15 obtains its measurements from an artery supplied by the internal carotid (the nasal septal anterior ethmoid artery) this sensor can obtain measurements when peripheral perfusion is relatively poor.

To ensure optimal performance, use an appropriate sensor, apply it as described in the sensor's Directions for Use, keep the sensor site at the level of the patient's heart, and always observe all warnings and cautions noted in the sensor's Directions for Use.

The sensors are sensitive to light. If excessive ambient light is present, cover the sensor site with opaque material to block the light. Failure to do so may result in inaccurate measurements. Light sources that can affect performance include surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps and direct sunlight.

1. Attach the sensor to the patient according to the instructions provided with the sensor. Be sure to read all warnings and cautions provided in the sensor's Directions for Use. Sensor placement is extremely important.
2. Plug the sensor into the SpO_2 sensor extension cable.
3. Snap the locking clip in place.
4. Plug the extension cable into the SpO_2 connector.
5. Lock the connector by turning the locking ring clockwise until it stops.

The SpO_2 channel will perform a self -calibration to assure measurement accuracy. SEARCH will then be displayed in the SpO_2 numeric window while the channel tries to detect blood pulsing through the measurement site.

6. Once the measurement has been established, observe the saturation value displayed in the numeric window.

WARNING

SENSORS EXPOSED TO AMBIENT LIGHT WHILE NOT APPLIED TO A PATIENT CAN EXHIBIT SEMI-NORMAL SATURATION READINGS. BE SURE THE SENSOR IS SECURELY PLACED ON THE PATIENT AND CHECK ITS APPLICATION OFTEN TO ENSURE ACCURATE READINGS.

If patient movement presents a problem, consider the following:

1. Make sure the sensor is secure and properly applied.
2. Apply ECG electrodes
3. Turn C-LOCK on:
   a) From the Main Menu, press *SENSORS.*
   b) Press *MORE*
   c) Press *SpO_2*.
   d) Press *MORE*
   e) Press *C-LOCK*.
4. Set *RESPONSE* to SLOW.
5. Press *MAIN MENU*.
6. Use a new sensor with fresh adhesive backing.
7. Move the sensor to a less active site.
8. Use a type of sensor that tolerates some patient motion, such as the D-25, d-20, or R-15.

NOTE

Special considerations are necessary when applying the oxygen sensor to the same limb used for cuff measurements. If the SpO_2 sensor and cuff are on the same limb, blood circulation to the pulse oximetry measurement site is temporarily impaired while the cuff occludes the limb artery during blood pressure measurements. This affects SpO_2 measurements and could create an SpO_2 patient alarm if limits are set for SpO_2. It is recommended that you place the SpO_2 sensor on a limb that is not used to obtain cuff measurements.

4.9.5 SpO_2 Settings

There are several waveform sizes to choose from. If the waveform is to be viewed all the time, you will need to turn on the SpO_2 waveform in the wave select window. You may also have to turn off other waveforms to continuously display the SpO_2 waveform.

1. From the MAIN MENU, press *SENSORS*.
2. Press *SpO_2*. (Press *MORE* then press *SpO_2*, if the physiological monitor includes an invasive pressure channel and CO_2).
3. Press *SIZE* to adjust the waveform for best viewing.
4. If necessary, adjust the placement of the sensor until a good SpO_2 waveform is displayed (Figure 4-14).

The waveform indicates the quality of the oxygen saturation measurement. A waveform with artifact may indicate erroneous oxygen saturation readings.

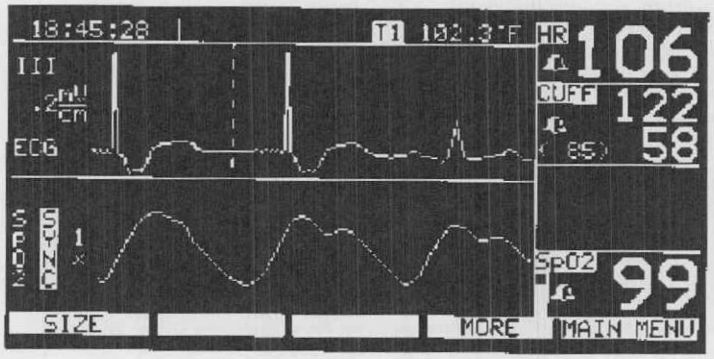


Figure 4-14. SpO_2 Waveform

5. Press *MORE* to display other SpO_2 functions. The SpO_2 waveform is removed, and the SpO_2 status window appears showing the current settings of RESPONSE and C-LOCK (Figure 4-15).

RESPONSE sets the time the Pulse Oximeter takes to acquire the oxygen saturation value. C-LOCK™ is a NELLCOR patented function that allows the Pulse Oximetry option to more accurately make oxygen saturation measurements.

6. Press *RESPONSE* to select the desired response time according to the guideline in Table 4-5.
7. Press *C-LOCK* to turn C-LOCK ON or OFF. With C-LOCK turned on, the saturation measurements are synchronized to each detected R-wave.

Systole is the basis of proper SpO_2 measurement. The Pulse Oximetry option recognizes systole as the highest pulse signal from the oxygen sensor. Artifact-induced pulses caused by patient movement and other conditions could be recognized as systole.

Synchronizing the pulse oximeter's systole determination to the R-wave reduces the effects artifact may have on SpO_2 measurements. C-LOCK should be turned ON to accurately determine SpO_2 on patients with movement or where other artifact affects the SpO_2 measurement. SYNC appears next to the waveform when synchronization to the ECG has been obtained. When SYNC is not displayed, the SpO_2 measurement is not synchronized. Synchronization takes a few seconds to establish the first time.

NOTE

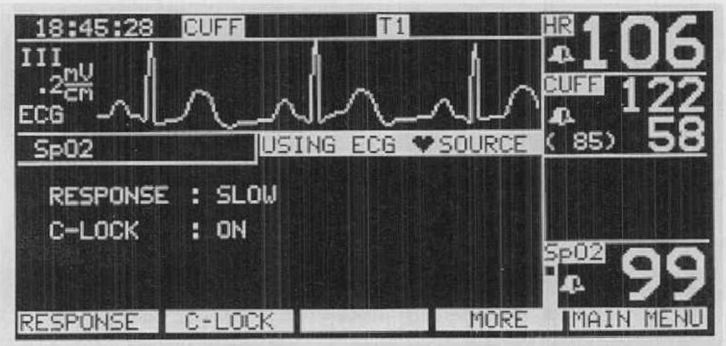
If monitoring ECG in addition to SpO_2, turn C-LOCK on.

If C-LOCK is on, the heart rate source is automatically set to ECG. An ECG signal must be present or C-LOCK does not activate.

When RESPONSE is set to FAST, C-LOCK is inhibited; however, it is not turned off. C-LOCK is automatically uninhibited if RESPONSE is set another mode.

If the patient is having frequent arrhythmias and SpO_2 alarms are frequent, turning C-LOCK off may improve performance and cause fewer alarms.

If the measurement is suspect, use another clinically accepted method of determining oxygen saturation.



RESPONSE : SLOW
C-LOCK : ON

Figure 4-15. The SpO_2 Status Window

Table 4-5. SpO2 Response Settings

Response	Time	Indications for Use
NORMAL	7 seconds	Relatively stable patients
SLOW	15 seconds	Patients exhibiting movement preventing accurate measurement at NORMAL setting
FAST	3 seconds	Special studies requiring fast readings (such as sleep studies) and where patient movement and other artifacts are not present

4.9.6 Setting SpO_2 Alarms.

Set the alarm limits according the your organizations protocols. Section 4.11 discusses alarms and alarm limits.

4.9.7 How SpO_2 is Displayed

SpO_2 displays a plethysmograph derived from the oxygen sensor, the oxygen saturation value as a percentage, and a pulse amplitude indicator (Figure 4-16) that shows the relative change in the pulsatile signal coming from the measurement site. The pulse amplitude indicator is helpful when the plethysmograph is not shown because other waveforms or a status window is displayed.

If the heart rate source is set to SpO_2, the pulses are counted to determine the pulse rate. The pulse rate measurement is displayed in the heart rate window. SpO_2 data is trended similarly to other patient data.

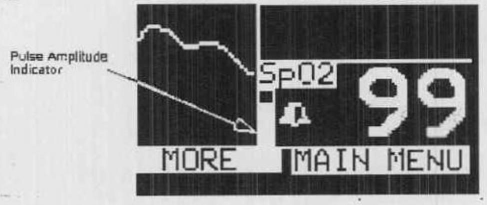


Figure 4-16. Pulse Amplitude Indicator

4.10 CO_2

The mainstream CO_2 non-invasively measures:

Inspired CO_2 ($INCO_2$)
End-tidal CO_2 ($ETCO_2$)
Breath Rate
Apnea.

WARNING

DO NOT USE MAINSTREAM CO_2 DURING MAGNETIC RESONANCE IMAGING (MRI) PROCEDURES. THE MAGNETIC FIELDS INVOLVED WILL PERMANENTLY DAMAGE THE CO_2 SENSOR.

4.10.1 Intended Use

The mainstream CO_2 is intended to for use only on adult and pediatric patients. Patients must either be intubated or breathing through a well fitting facemask connected to a breathing system such as an anesthesia circle system. It is not recommended for use on neonates.

The mainstream CO_2 operating altitude is -2,000 to 15,000 ft. The Physiological Monitor automatically continuously makes corrections for altitude. No manual entry or correction is required.

CO_2 should only be used with the mainstream sensor and single-use airway adapter. When using CO_2 in critical care, the adapter should be replaced every 24 hours or sooner if it becomes occluded.

CO_2 reading accuracy is affected by the presence of interfering gases and vapors. If CO_2 is used on patients who are being administered oxygen (O_2) or nitrous oxide (N_2O), be sure to set the appropriate compensation setting using the *GAS COMP* button.

CO_2 processing and sensor should be verified every 6 months for compliance with operating specifications.

4.10.2 CO_2 Measurements

The Physiological monitor Mainstream CO_2 determines carbon dioxide content of a patient's inhaled and exhaled breath. A mainstream sensor is attached to an airway adapter in series with a ventilator's patient breathing circuit. A CO_2 waveform can be displayed on the Physiological monitor, and end-tidal CO_2 ($ETCO_2$) and inspired CO_2 ($INCO_2$) numeric values are shown.

Displayed values of $ETCO_2$ and $INCO_2$ are the highest and lowest values (respectively) of CO_2 measured during the time interval set by the RESPONSE setting. $INCO_2$ numerics are shown only when they are too high.
Alarm limits can be set for both measurements. Only a high Alarm limit can be set for $INCO_2$.

Breath Rate Measurements

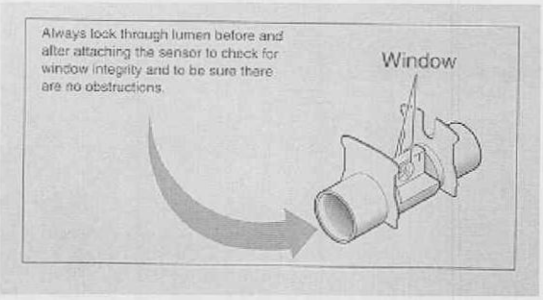
Breath Rate (BR) is determined from the CO_2 sensor and displayed numerically on the display next to the CO_2 values. Upper and lower alarm limits can be set for BR.

Apnea Events

Apnea events are detected from the CO_2 sensor. Apnea delay can be set to 15, 20, 25, or 30, seconds. The Physiological monitor initiates an alarm in response to each apnea event.

4.10.3 CO_2 Connection

1. Remove an airway adapter from its plastic bag
2. Inspect it for any obstructions in the lumen and for window integrity (Figure 4-17)



Always look through lumen before and after attaching the sensor to check for window integrity and to be sure there are no obstructions.

Figure 4-17. CO_2 Measurement Airway Adapter

3. Holding the airway adapter in one hand and the sensor in the other, align the sensor over the adapter and between the protruding "tabs" as shown in Figure 4-18.

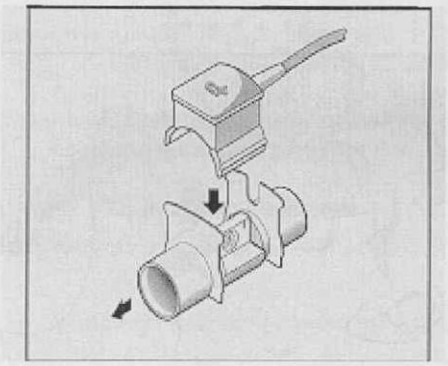


Figure 4-18. Attaching CO_2 Sensor to the Adapter

4. Gently slide the sensor onto the airway adapter using a downward motion and keeping the sensor properly aligned.

WARNING

ALWAYS GENTLY ATTACH THE SENSOR TO THE AIRWAY ADAPTER AWAY FROM THE PATIENT, AND TAKE CARE NOT TO DAMAGE THE GLASS WINDOWS.

CAUTION

If the sensor does not easily slide onto the adapter in the next step, do not attempt to force these components together. They fit together only one way.

The sensor will quietly snap into place.

5. After the sensor is in place, check the airway adapter again by looking through the lumen. The windows should be intact.
6. Gently push and twist the **larger** end of the adapter onto the patient's tracheal or endotrachael tube (Figure 4-19)
7. Gently push and twist the **smaller** end of the adapter onto the ventilator circuit tubing (Figure 4-19).
8. Check to make sure both connections are tight to prevent air leaks.

WARNING

WHEN ATTACHING THE AIRWAY ADAPTER IN THE NEXT STEPS, POSITION THE ADAPTER SO THAT THE SENSOR IS ON TOP AS SHOWN IN Figure TO AVOID FLUID COLLECTION IN THE SENSOR AIRWAY SLOT. ANY CONCENTRATION OF FLUIDS HERE CAN CAUSE INACCURATE CO_2 READINGS.

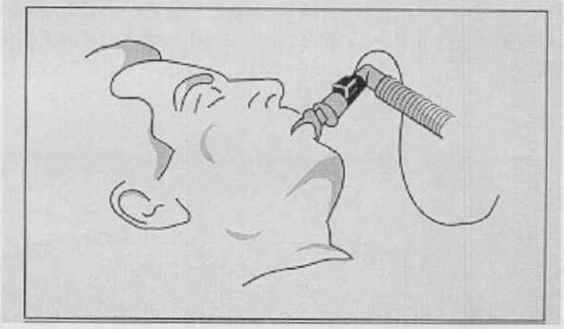


Figure 4-19. Positioning CO_2 Sensor On Top

9. Plug in the CO_2 sensor cable to the CO_2 connector (Figure 4-2).

WARNING

ALWAYS DOUBLE CHECK TO ENSURE THAT THERE ARE NO LEAKS IN THE BREATHING CIRCUIT AT ANY POINT OF CONNECTION.

10. Observe the physiological monitor display. Observe WARM UP appears in the CO_2 numerics zone and the CO_2 waveform is displayed without a value range.

Warm-up time is typically 20 seconds, after which the CO_2 measurement and waveform range are displayed.

4.10.4 CO_2 Settings

From the Main Menu:

1. Press *SENSORS*.
2. Press *MORE*. Do not press *MORE* if the monitor has no invasive pressure channels.
3. Press *CO_2* to reach the first CO_2 Menu.
4. Press *RANGE* until the desired waveform scale range appears on the display. The range choices are shown in Table 4-6.
5. Press *MORE* to view the CO_2 status window (Figure 4-20).

NOTE

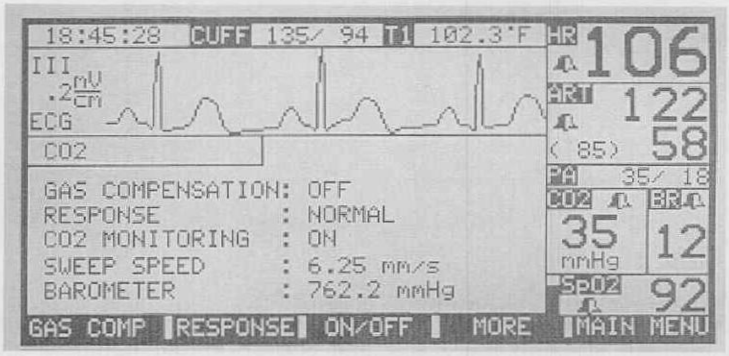
If an inspired value is displayed indicating patient rebreathing (non-zero inspired CO_2), check the patient breathing circuit for proper function. Verify the sensor calibration against room air. If the Physiological monitor continues to display inspired values, remove and replace the sensor.

If the $ETCO_2$ value is displayed as +++, the sensor could be damaged. Verify calibration against a known reference gas. If the sensor does not verify, remove and replace the sensor.

Table 4-6. CO2 Range Values

Units	Waveform Scale Range
mmHG	0-100 0-60 (default setting) 0-30
kPa	0-14 0-10 0-4
%	0-14 0-10 0-4

6. Press the *GAS COMP* button if either O_2 or N_2O is being administered to set the proper gas compensation as shown in Table 4-7. If no other gas is being administered, set the *GAS COMP* to *OFF*. *OFF* is the default setting.



```
GAS COMPENSATION: OFF
RESPONSE        : NORMAL
CO2 MONITORING  : ON
SWEEP SPEED     : 6.25 mm/s
BAROMETER       : 762.2 mmHg
```

Figure 4-20. CO_2 Status Window

Table 4-7. Gas Compensation Values

Gas Administration Level/ GAS COMP Setting	$ETCO_2$ or $INCO_2$ Value
OFF	CO_2 value = actual CO_2 value
O_2>50%, No N_2O	CO_2 value = actual CO_2 value x 1.03
N_2O > 50%	CO_2 value = actual CO_2 value x 0.952

7. Press *RESPONSE* to select either NORMAL, SLOW, or FAST. The FAST setting is recommended where a sudden step change in $ETCO_2$ is of concern, such as that induced by an air embolus in certain neurosurgical procedures. A SLOW response will decrease $ETCO_2$ false alarms when breath morphology varies considerably from one breath to the next. The default setting is NORMAL. Table 4-8. CO2 Response Settings elaborates.

Table 4-8. CO2 Response Settings

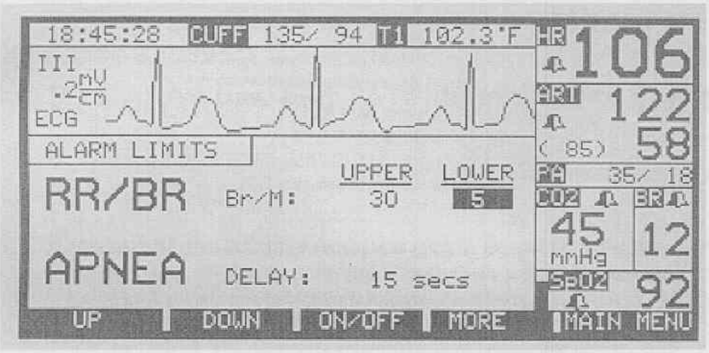
Response Time Setting	Time Period of Sampling	Typical Indications for Use
FAST	15 seconds	During neuroanesthesia
NORMAL	30 seconds	During routine use
SLOW	45 seconds	To decrease $ETCO_2$ false alarms

8. Press *MORE*.
9. Press *mm/sec* to select 3.13, 6.25, or 12.5 mm/sec. The default setting is 6.25 mm/sec.
10. Set upper and lower alarm limits for $ETCO_2$.
11. Set only an upper alarm limit for $INCO_2$.
12. Set both upper and lower Breath rate alarm limits.
13. Set the alarm limit for Apnea Delay.

WARNING

TO ENSURE PATIENT SAFETY, IT IS RECOMMENDED THAT THE BREATH RATE ALARM LIMITS ALWAYS BE TURNED ON AND SET APPROPRIATELY.

Apnea Delay is the number of seconds that elapse before the alarm sounds when the next breath is not detected. The default setting is 20 seconds. Once the first breath has been detected, the Apnea alarm limit setting is always turned on, as long as the CO_2 channel is active. The BR and Apnea Alarm limit window is shown in Figure 4-21. STAT SET does not affect the Apnea limit. During an Apnea Alarm the CO_2 waveform is always displayed on the physiological monitor screen.



18:45:28
CUFF 135/ 94
T1 102.3°F
HR 106
III
.2 mV/cm
ECG
ART 122
(85) 58
PA 35/ 18
CO2 45 mmHg
BR 12
SpO2 92
ALARM LIMITS
UP
DOWN
ON/OFF
MORE
MAIN MENU

RR/BR Br/M: UPPER 30 LOWER 5

APNEA DELAY: 15 secs

Figure 4-21. Breath Rate and Apnea Alarm Limit Status Window

4.10.5 The CO_2 ON/OFF Button

CO_2 monitoring begins automatically when the sensor is plugged in. The *ON/OFF* button allows disabling of CO_2 monitoring without removing the sensor.

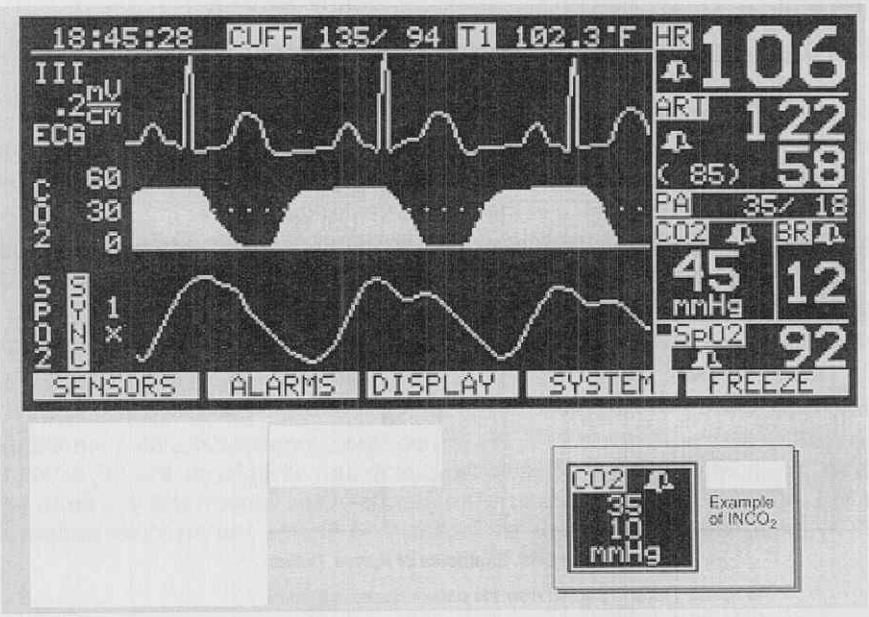
When monitoring status is off, OFF is shown in place of CO_2 and BR numerics. An equipment alert is displayed if the CO_2 sensor is disconnected. The waveform window remains active until the CO_2 waveform in Display Wave Select window is turned off.

4.10.6 How CO_2 is Displayed

CO_2 levels are normally displayed in two forms (Figure 4-22):

A CO_2 waveform and an end-tidal CO_2 ($ETCO_2$) numeric value

When inspired CO_2 ($INCO_2$) numeric values are at alarm levels greater than 7.5 mmHg (1 kPa or 1%), they are shown numerically along with the $ETCO_2$ value. The measured breath rate (BR) is displayed to the right of the CO_2 values.



18:45:28
CUFF 135/ 94
T1 102.3°F
HR 106
III
.2 mV/cm
ECG
CO2
60
30
0
SPO2
SYNC
1 x
ART 122
(85) 58
PA 35/ 18
CO2 45 mmHg
BR 12
SpO2 92
SENSORS
ALARMS
DISPLAY
SYSTEM
FREEZE
CO2 35 10 mmHg
Example of INCO2

Figure 4-22. CO_2 waveform and Breath Rate Numerics

4.11 Setting Alarm Limits

4.11.1 The Quickest Way to Set Limits (STAT SET and PARAM SET)

To immediately set alarm limits:

1. From the Main Menu, press *ALARMS*.
2. Press *STAT SET*.

The physiological monitor quickly turns on all alarm limits and calculates the alarm limits for all vital signs that are being monitored. The calculated values are based on the patient's current values as shown in Table 4-9.

Table 4-9. Stat Set and Param Set Limit Calculations

Parameter	Lower Limit	Upper Limit
Heart Rate	HR x 0.8 + 5	HR x 0.8 + 50
Cuff Systolic	SYS x 0.68	SYS x 0.86 + 38
Cuff Diastolic	DIA x 0.68 + 6	DIA x 0.86 + 32
Cuff Mean	MN x 0.68 + 8	MN x 0.86 + 35
Invasive Pressure ≤ 25	Invasive Pressure - 5	Invasive Pressure + 5
Invasive Pressure = 26 to 99	Invasive Pressure x 0.8	Invasive Pressure x 1.2
Invasive Pressure ≥ 100	Invasive Pressure -20	Invasive Pressure + 20
Temperature	Temp - 0.5	Temp + 0.5
SpO_2<95	SpO_2 - 5	100
SpO_2≥95	90	100
$ETCO_2$	5 mmHg -0.7 for % and kPa	+10 mmHg +1.4 for % and kPa
$INCO_2$	N/A	$INCO_2$ + 5 $INCO_2$ + 0.7 for % and kPa
Breath Rate (BR)	BR x 0.5	BR x 1.5
Apnea Delay	is not affected by STAT SET	is not affected by STAT SET

3. Press *PARAM SET* to quickly set alarm limits for just one vital sign.

PARAM SET automatically calculates the alarm limits in the same way STAT SET does however, PARAM SET only affects the vital sign parameters you select with the NXT PAGE button.

4. Use *PARAM OFF* to turn off all limits for just the selected parameter.

When you first select a vital sign parameter's window you will se the *PARAM OFF* button if limits are already set for the parameter (Figure 4-23) and you will see the *PARAM SET* button if no limits are set.

5. Press *PARAM OFF* once and then press *PARAM SET* to reset limits for just one parameter. This process first turns off limits and then recalculates and resets limits just for the selected parameter

4.11.2 Turning On and Off All Limits

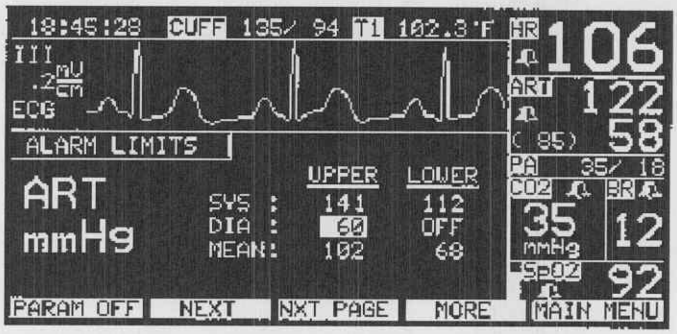
Whenever you press *STAT SET* or *PARAM SET*, the physiological monitor calculates the alarm limits and turns them on, only for monitored channels. If you only want to turn all limits on and off, without changing their values, press *ALL ALRM* in the Alarms Menu. The Alarms status window lets you know when all alarms are on or off by the displayed bells. Refer to Section 4.13 Alarms and Alerts for additional information.

4.11.3 Changing Individual Limits

Sometimes it is necessary to set or change a single alarm limit. You must then set each alarm limit according to you organization's protocols. Or program the physiological monitor to turn on with the limits you want (refer to Changing Power-On Settings, paragraph 4.4.4).

1. Press *ALARMS* from the Main Menu.
2. Press *LIMITS* to display the alarm limits window and the Limits Menu (Figure 4-23).

3. Press *NXT PAGE* to change the desired alarm limit window.
4. Press *NEXT* to move the cursor. Continue to press *NEXT* until the desired limit is selected.
5. Press *MORE* to select the Limits Adjust Menu.
6. Press *ON/OFF*, *UP*, or *DOWN* to set the limit to the desired limit value.
7. When the limit is set, press *MORE*.
8. Press *NEXT* to select the next limit or press *NXT PAGE* to select another vital sign.
9. Continue until all the desired limits are set.


18:45:28
CUFF 135/ 94
T1 102.3°F
HR 106
III
.2 mV/cm
ECG
ART 122 58
(85)
PA 35/ 18
CO2 35 mmHg
BR 12
SpO2 92
ALARM LIMITS
ART
mmHg
UPPER
LOWER
SYS : 141 112
DIA : 60 OFF
MEAN: 102 68
PARAM OFF
NEXT
NXT PAGE
MORE
MAIN MENU

Select limits by pressing the NEXT button and then pressing the MORE button to access the Limits Adjust menu (below). Adjust limits by pressing the UP and DOWN buttons. Select the next limit by pressing the MORE button and the NEXT button. Select the next vital sign by pressing the NXT PAGE button.

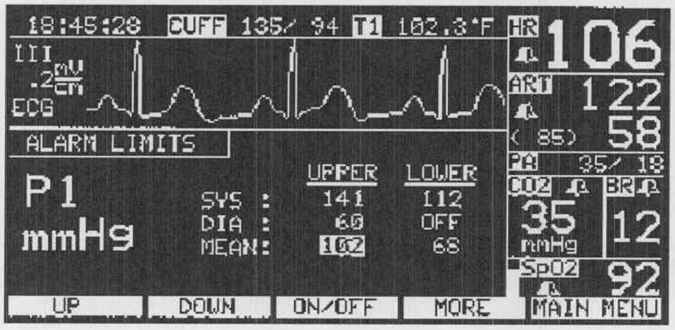

18:45:28
CUFF 135/ 94
T1 102.3°F
HR 106
III
.2 mV/cm
ECG
ART 122 58
(85)
PA 35/ 18
CO2 35 mmHg
BR 12
SpO2 92
ALARM LIMITS
P1
mmHg
UPPER
LOWER
SYS : 141 112
DIA : 60 OFF
MEAN: 102 68
UP
DOWN
ON/OFF
MORE
MAIN MENU

Figure 4-23. Alarm Limits Menus and Limits Windows

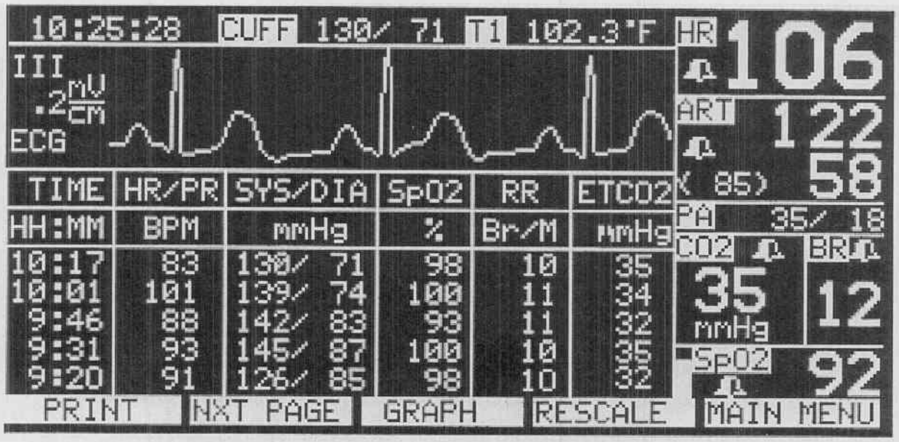
4.12 Trends.

The physiological monitor can show you a patient's vital signs over the last several hours. Every two minutes, the physiological monitor averages the monitors' vital signs and stores them in its trend memory, which can save the last eight hours of trend information, the last five of which can be viewed on the display. Trends can be viewed as a table (tabular) or as a graph (graphical trends).

4.12.1 Tabular Trends.

A tabular trend shows you the last five noninvasive blood pressures, SpO_2, CO_2, and breath rate readings as a table (Figure 4-24).

The table shows the time, systolic, diastolic and mean pressures, the pulse rate determined for each cuff measurement, and the SpO_2 value at the time the cuff measurement was taken, if available. If the physiological monitor was set to automatically take noninvasive pressure measurements at a selected interval, you can easily determine the interval by checking the time column.


10:25:28
CUFF 130/ 71
T1 102.3°F
HR 106
III
.2 mV/cm
ECG
ART 122
(85) 58
PA 35/ 18
CO2
BR
35 mmHg
12
SpO2 92
PRINT
NXT PAGE
GRAPH
RESCALE
MAIN MENU

TIME	HR/PR	SYS/DIA	SpO2	RR	ETCO2
HH:MM	BPM	mmHg	%	Br/M	mmHg
10:17	83	130/ 71	98	10	35
10:01	101	139/ 74	100	11	34
9:46	88	142/ 83	93	11	32
9:31	93	145/ 87	100	10	35
9:20	91	126/ 85	98	10	32

Figure 4-24. Tabular Trends

4.12.2 Graphical Trends.

A graphical trend shows the trend values plotted against time with each point representing the patient's vital signs averaged over a two minute period.

Except for cuff, all vital signs are continuously monitored from the time monitoring begins to the time it ends. If a monitored vital sign value dramatically changes (for example, goes to zero) at any time during monitoring, the value is considered a "real" value and averaged with other values, which affects the displayed trend value. This dramatic change can show up in the trend as a large difference between adjacent trend points. Continuously monitored values are always trended, except for the cuff measurement.

There are three types of trend graphs: single point, two point, and three point graphs. Table 4-10 lists the types of graphs displayed.

Table 4-10. Graphical Trends

Points Graphed	Parameter Graphed	Figure Reference
Single-Point	Heart Rate, Breath Rate, SpO_2, Single Temperature	Figure 4-25
Two-Point	Two Temperatures, CO_2	Figure 4-26
Three-Point	Cuff, Invasive Blood Pressure	Figure 4-27

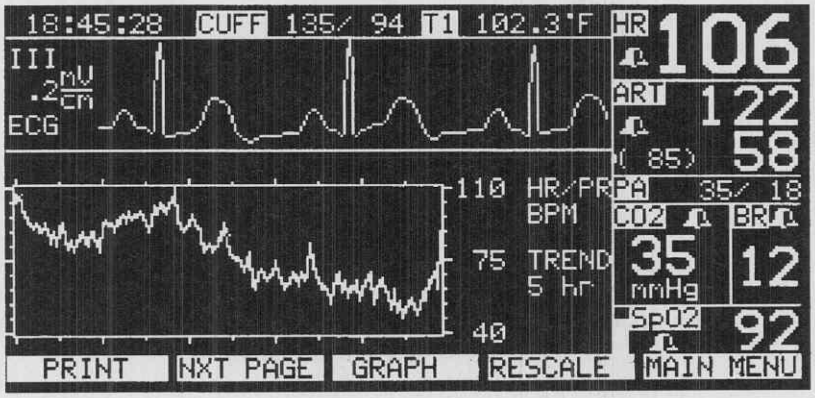

10:45:28
CUFF 135/ 94
T1 102.3°F
HR 106
III
.2 mV/cm
ECG
ART 122
(85) 58
PA 35/ 18
CO2
BR
35 mmHg
12
SpO2 92
110
75
40
HR/PR BPM
TREND 5 hr
PRINT
NXT PAGE
GRAPH
RESCALE
MAIN MENU

Figure 4-25. Single Point Graph

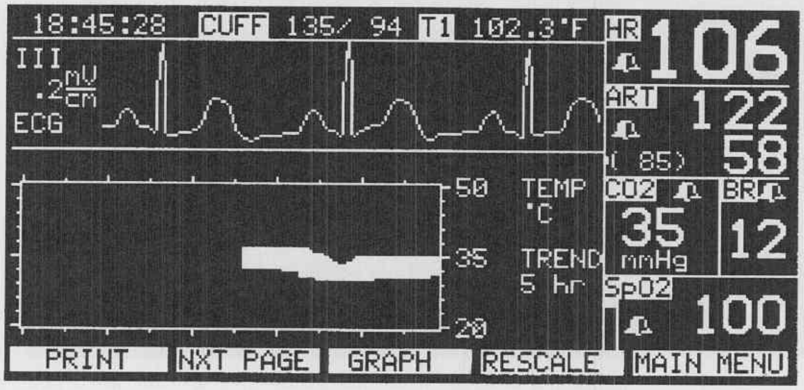

18:45:28
CUFF 135/ 94
T1 102.3°F
HR
106
III
.2 mV/cm
ECG
ART
122
(85)
58
50
35
20
TEMP
°C
TREND
5 hr
CO2
35
mmHg
BR
12
SpO2
100
PRINT
NXT PAGE
GRAPH
RESCALE
MAIN MENU

Figure 4-26. Two Point Graph

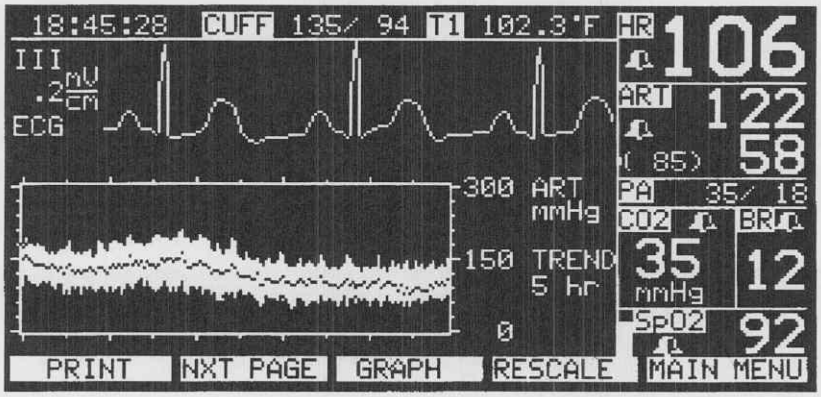

18:45:28
CUFF 135/ 94
T1 102.3°F
HR
106
III
.2 mV/cm
ECG
ART
122
(85)
58
PA 35/ 18
300
150
0
ART
mmHg
TREND
5 hr
CO2
35
mmHg
BR
12
SpO2
92
PRINT
NXT PAGE
GRAPH
RESCALE
MAIN MENU

Figure 4-27. Three Point Graph

Cuff is a special graphical trend situation. Cuff is not measured continuously like other vital sign parameters; cuff measurements are "discontinuous". The smallest interval at which the physiological monitor can take cuff measurements is 30 seconds, except for the TURBOCUF mode. The longest automatic cuff interval is 60 minutes.

When trends are averaged every two minutes, the physiological monitor averages only the cuff measurements actually taken. If the physiological monitor obtained cuff measurements only twice over a two-minute period, then only the results of those two measurements are averaged. Figure 4-28 shows graphed cuff measurements. The physiological monitor's cuff measurements are accurately trended.

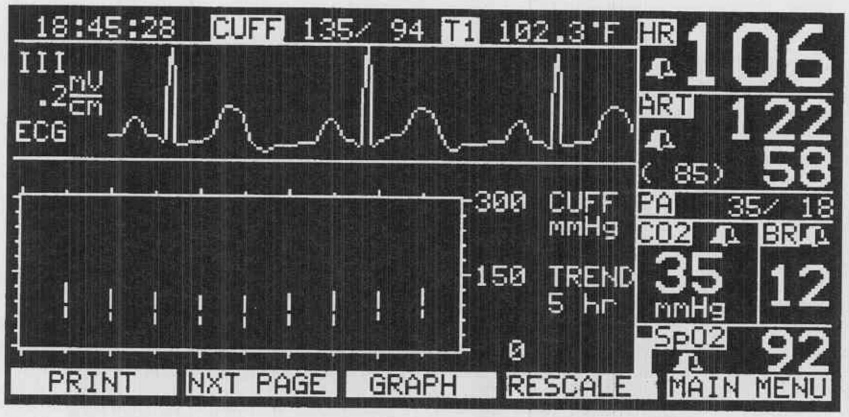

18:45:28
CUFF 135/ 94
T1 102.3°F
HR 106
III
.2 mV/cm
ECG
ART 122
(85) 58
PA 35/ 18
CO2
BR
35
mmHg
12
SpO2 92
300
150
0
CUFF mmHg
TREND 5 hr
PRINT
NXT PAGE
GRAPH
RESCALE
MAIN MENU

Figure 4-28. Cuff Trend

4.12.3 Displaying Trends.

Displayed Trends show the last five hours of data. Trends are displayed only if you have one waveform turned on in the wave selection window, or, if more than one waveform is displayed, when you press the *TREND* button in the Display Menu.

4.12.4 Trend Menu

The Trend Menu allows you to select trended data for display, and change the scales of the displayed trend. The Trend Menu is accessed by pressing the *DISPLAY* and then *TREND.* Figure 4-29 shows a Trend Menu.

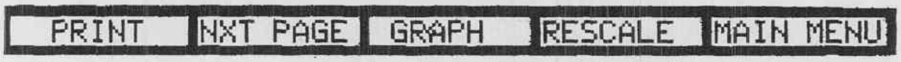

PRINT
NXT PAGE
GRAPH
RESCALE
MAIN MENU

Figure 4-29. Trend Menu

Selecting a Trend (*NXT PAGE*)

All vital sign parameters are shown on their own trend graph. You select the trend you want displayed by pressing the *NXT PAGE* button. The trend is identified by a label to the right of the scale. The trend labels are:

HR/PR source for heart rate/pulse rate as selected by the HR/PR source with the Display menu

P1, P2, ART, PA, CVP, and ICP for invasive pressures (the trend uses the selected label)

ETCO$_2$ for end-tidal CO$_2$

INCO$_2$ for inspired CO$_2$

BR for breath rate derived from CO$_2$

CUFF for noninvasive pressures

SpO$_2$ for oxygen saturation

TEMP for T1 and ΔT.

Changing the Trend Scale (Graph and Rescale).

> NOTE
>
> *RESCALE* considers the last 8 hours of trend information and includes data that may not be visible on the display.

Each parameter has three scales to allow the best viewing of the trend. Besides the three scales, the cuff trend can also show in a table the last five cuff measurements with the time and pulse rate. Select the desired scale by pressing the *GRAPH* button. The scales for each trend are listed in Table 4-11.

The physiological monitor also has the capability to automatically select the best graph for the current trend values with its rescale function. Each time you press the *RESCALE* button, the physiological monitor examines the highest and lowest values for each trend and automatically selects the scale for the best viewing of the trend.

Table 4-11. Trend Display Scales

Vital Sign Parameter	Lowest Values	Highest Values
Heart Rate /Pulse Rate	0	250
	25	125
	50	100
Invasive Pressure	0	300
	30	180
	-30	70
Carbon Dioxide (CO_2) mmHg	0	100
	0	60
	0	30
Carbon Dioxide (CO_2) kPa	0	14
	0	8
	0	4
Carbon Dioxide (CO_2) %	0	14
	0	8
	0	4
Breath Rate (BR)	0	150
	0	50
	0	20
SpO_2	0	100
	60	100
	80	100
Cuff	0	300
	0	150
	50	100
	Table of last five	Table of last Five
Temperature (°F)	60	130
	90	110
	95	105
Temperature (°C)	10	50
	25	45
	30	40

4.12.5 Default Settings

The physiological monitor is delivered with factory defaults (Table 4-12).

Table 4-12. Factory Default Settings

Function	Default Setting
Date	MO/DA/YR.
Decimal	. (Period)
Contrast	3rd out of 11 steps
mm/sec.	25 mm/sec.
Alarm Tone	MEDIUM
HR/PR TONE	LOW

Function	Default Setting
HR/PR SOURCE	ECG
ECG Size	1 mV/cm
ECG Lead	II
ECG Filter	60 Hz.
ECG Pacer	ON
IBP Range	0 to 180 mmHg
IBP Rescale	0 to 140 mmHg
IBP Mode	RESCALE
Invasive Pressure Formats	SDm
Cuff Mode	MANUAL
Cuff Auto Time	15 Min
SpO$_2$ SIZE	2x
SpO$_2$ C-LOCK	ON
SpO$_2$ Response	NORMAL
TEMP F/C	Celsius
CO$_2$ Range	0 to 60 mmHg
CO$_2$ Sweep	6.25 mm/sec
CO$_2$ Units	mmHg.
CO2 Gas Compensation	OFF (cannot be programmed)
Display Wave Select	All waves are on except Cuff
Trend Parameter	Cuff
Alarm Limits	All are ON except P2
HR limits	50, 120 BPM
CUFF Limits	SYS- 75, 240 mmHg DIA - 35, 130 mmHg MEAN - 50, 140 mmHg
P1, P2 Limits	SYS - 75, 240 mmHg DIA - 35, 130 mmHg MEAN - 50, 140 mmHg
SpO$_2$ Limits	85%, 100%
TEMP Limits	35.0^{O} 37.8^{O} C
ΔT Limits	0.0^{O}, 2.8^{O} C
ETCO$_2$ Limits	25, 60 mmHg (3, 8 for % and kPa)
INCO$_2$ Limits	N/A, 5 mmHg (0.7 for % and kPa)
Breath Rate (BR) Limits	5, 30 Br/M
Apnea Delay	20 seconds
TREND Graphs	
HR	25 to 125 bpm
CUFF	Tabular
IBP	30 to 180 mmHg
SpO$_2$	80% to 100%
TEMP	25^{O} TO 45^{O} C
CO$_2$	0 to 60 mmHg
BR	0 to 50 Br/M

4.13 Alarms and Alerts

4.13.1 Alarms - General

The alarms status window and Alarms Menu appear when ALARMS is pressed in the Main Menu (Figure 4-30). Immediate indications and controls are given. The Alarms status window indicates the alarms status of each vital sign parameter. The presence of a bell symbol (full or half) shows that the alarm limits are turned on and set for the vital sign parameter. The full bell indicates all alarm limits are turned on. The half bell indicates at least one alarm limit is turned off. The absence of a bell shows that no alarm limits are turned on. Bells only appear when at least one limit is turned on and the vital sign parameter is being monitored.

The Alarms Menu is shown below the status window and allows access to other alarm functions to automatically set alarm limits or individually set them. The menu also allows for silencing the alarm tone that occurs when a limit is violated. The Alarm tone can be adjusted to one of three volumes. The tone can never be completely turned off. (Use the SUSPEND soft key to temporarily suspend the tone).

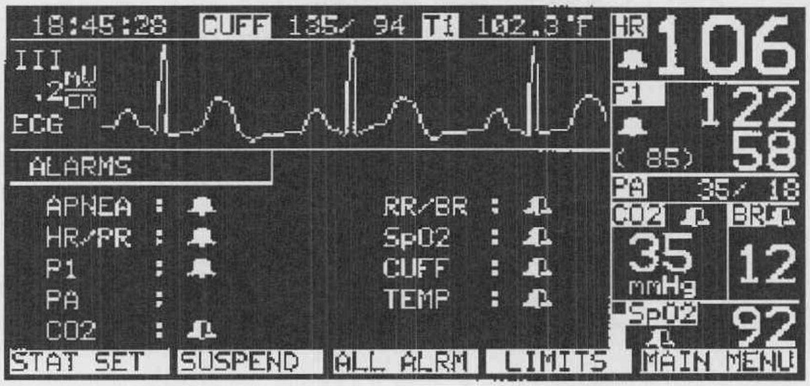
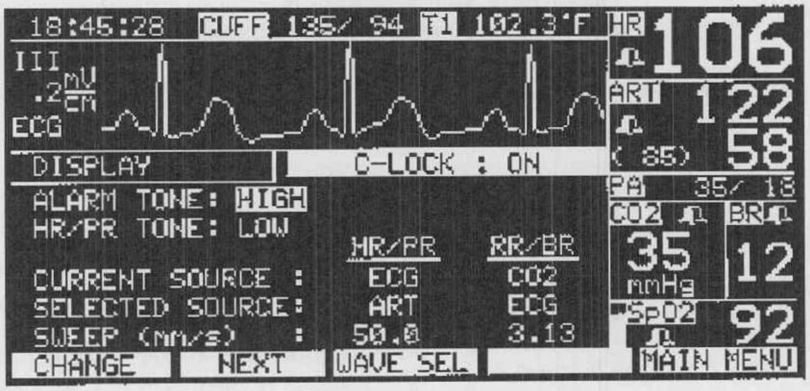

18:45:28
CUFF 135/ 94
T1 102.3°F
HR 106
III .2 mV/cm
ECG
P1 122
(85) 58
PA 35/ 18
CO2
BR
35 mmHg
12
SpO2 92
ALARMS
APNEA :
HR/PR :
P1 :
PA :
CO2 :
RR/BR :
SpO2 :
CUFF :
TEMP :
STAT SET
SUSPEND
ALL ALRM
LIMITS
MAIN MENU

Figure 4-30. Alarm Status Window

To set the tone through the Display Menu:

1. Press DISPLAY, MORE, and MORE again. The Display status window will appear.
2. Use the NEXT soft key to select the Alarm Tone function.
3. Use the CHANGE soft key to change alarm tone settings (Figure 4-31).


18:45:28
CUFF 135/ 94
T1 102.3°F
HR 106
III .2 mV/cm
ECG
ART 122
(85) 58
PA 35/ 18
CO2
BR
35 mmHg
12
SpO2 92
DISPLAY
CHANGE
NEXT
WAVE SEL
MAIN MENU

C-LOCK : ON

ALARM TONE: HIGH
HR/PR TONE: LOW

	HR/PR	RR/BR
CURRENT SOURCE :	ECG	CO2
SELECTED SOURCE:	ART	ECG
SWEEP (mm/s) :	50.0	3.13

Figure 4-31. Alarm Tone Setting

4.13.2 Alarm Types

A steady, high pitched, clearly audible alarm tone sounds whenever a limit is violated on most patient channels. The tone for SpO_2 alarms is lower in frequency. In addition, Apnea alarm tone is one second on, one second off. Table 4-13 summarizes alarm indications.

The alarm tone continues until:

The patient condition changes and no longer violates the limit,

The alarm tone is suspended by pressing the SUSPEND soft key,

The alarm limit is reset so the vital sign does not violate it.

The alarm limit is turned off.

Table 4-13. Alarm Indications

Alarm Light	Alarm(s) OFF Light	Tone	Numeric	Bell	Condition
OFF	ON	OFF	ON	OFF	No alarm and alarms off.
ON	ON	ON	FLASH	ON	Patient alarm and at least one alarm on.
ON	OFF	ON	FLASH	ON	Patient alarm and all alarms on.
ON	X[a]	OFF	ON	ON	Temporary Patient alarm. Check Alarms Parameter window for parameter that caused alarm[b]
OFF	FLASH	OFF	ON	X[c]	No Alarm and Alarms suspended
FLASH	OFF	OFF	FLASH	ON	Suspended patient alarms.

[a] The state of this light does not matter for the condition.

[b] To turn off the ALARM light, view each alarms parameter window until the light is found with an asterisk (*) next to it. This limit caused the alarm. (It is possible to have more than one parameter cause a temporary alarm.) The asterisk(s) are cleared when the alarms parameter window is removed by pressing the MAIN MENU soft key.

[c] The state of the bell (ON or OFF) indicates whether alarms were on or off before they were suspended.

Alarm Hold-Offs.

Motion Artifact or other factors can cause false vital sign alarms. To help minimize false alarms the PM briefly delays or "holds off" triggering alarms for certain vital sign limit violations.

After the alarm hold-off period begins, if the monitor detects that the patients vital sign has returned to acceptable limits, the PM cancels the alarm hold-off. The next time a vital sign limit is violated, the PM starts a new alarm hold-off period. Table 4-14 summarizes the alarm hold-off periods.

Table 4-14. Alarm Hold-Offs

Monitoring Function	Alarm Hold-off Time Period
HR/PR	3 seconds
SpO_2	10 seconds
RR/BR	5 seconds

Life Threatening Alarms.

A life threatening alarm is the highest priority patient alarm. You are notified of any life-threatening alarm as soon as it is detected regardless of any other patient alarms or equipment alerts. An apnea alarm is an example of a life threatening alarm.

During a response to a life threatening alarm you can **SUSPEND** the arm tone and adjust the Alarm Limits. The **STAT SET** and **ALL ALRM** buttons are not available for life threatening alarms.

WARNING

SUSPENDING AN ALARM TONE ALSO SUSPENDS ALL ALARM MONITORING FOR 90 SECONDS OR UNTIL THE RESUME BUTTON IS PRESSED.

During a response to a patient alarm, typically the first thing you will do is temporarily turn off the alarm tone. You can immediately do this by pressing the **SUSPEND** button in the Patient Alarm Menu, which is automatically displayed as soon as the alarm occurs. The tone is suspended only for 90 seconds with all alarm monitoring. After that period, the tone will again sound if the alarm condition still exists; alarm monitoring will also resume. You can "unsuspend" the alarm before 90 seconds has elapsed by pressing the **RESUME** button in the Alarms Menu. If an Alarm condition still exists, the tone will again sound.

When you suspend the alarm, the Patient Alarm Menu is removed, and the red ALARM light begins to slowly flash, indicating a suspended patient alarm condition. If you were looking at the patient's trends on the PM or making some other monitor setting adjustments prior to the alarm, whatever was displayed prior to the alarm is again displayed. Once the alarm tone has been suspended and the patient's condition has been assessed and responded to, you can make the physiological monitor alarm adjustments if necessary. Possible adjustments to cancel the alarm follow.

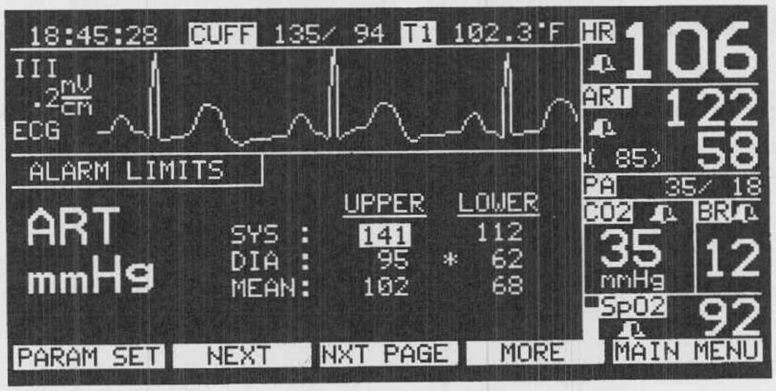
If the alarm is suspended:

1. Turn off all alarm limits by pressing **ALL ALRM** in the Alarms Menu (**ALARMS>ALL ALRM**)
2. Automatically recalculate and reset all alarm limit values so they do not produce a violation by pressing **STAT SET** in the Alarms Menu (**ALARMS** > **STAT SET**).
3. Turn off the alarm limits only for the violating vital sign by pressing **PARAM OFF** in the Limits Menu once the appropriate vital sign *limits window* is selected (**ALARMS** > **LIMITS** > **NXT PAGE**> **PARAM OFF**); all limits for the violating vital sign are turned off.
4. Automatically recalculate and reset the limits only for the violating vital sign by pressing **PARAM OFF** and then **PARAM SET** in the Limits Menu once you've selected the appropriate vital sign *limits window.*
5. Manually change the violated alarm limit value by selecting the violated limit value and adjusting it or turning it off.

Temporary Alarm

During a temporary alarm, typically you will first want to find out which vital sign violated its limit. Since the condition that caused the alarm no longer exists, the alarm tone no longer sounds and the Patient Alarm Menu is not displayed.

1. Press **ALARMS** and then **LIMITS** to display the first limits window (Figure 4-32).
2. Look for an asterisk (*) next to a limit.
3. Once the asterisk is located, the ***ALARM*** light turns off.
4. Press **NXT PAGE** until all asterisks are located (in the event of multiple alarm violations).



ART mmHg

	UPPER		LOWER
SYS :	141		112
DIA :	95	*	62
MEAN:	102		68

Figure 4-32. Alarm Limits Status Window

4.13.3 Alerts

An equipment alert consists of a high pitched, clearly audible alarm tone sounding for one second and then four seconds of silence. This tone will repeat until the equipment or condition is corrected. The equipment alert window will appear on the display identifying the faulty equipment condition. Some equipment conditions also result in a caution message alternating with the time of day, cuff, or temp numerics to the left of the heart rate. Table 4-15 through Table 4-22 define alert messages, condition, and corrective action(s) for system and subsystems of the physiological monitor.

Table 4-15. Physiological Monitor Failures and Fatal Error Codes

Message	Condition	Corrective Action
None	PM fails to Power-On	Check if LSTAT on. If on, re-attempt PM Power-on. If no success contact IMS support.
None	PM Power On, No screen	Re-attempt Power-On. Press the middle button below the screen (the CONTRAST button) until you can see the display. If you still cannot see the display, turn off the monitor, turn it back on, then press the middle button again. If the monitor screen remains dark, the PM may need servicing. Refer to section 5, Table 5-2 and Appendix E of this manual for further information.
None	Soft keys do not function	Recycle power to PM. If no success contact IMS support.
None	LSTAT dropped, in an accident or suspected rough handling	Complete Functional Verification and Safety Check.
None	Suspected malfunction with all or part of functions	Functional Verification of suspected functions.
None	Monitor fails functional verification	Contact IMS support. Calibration of PM will be required.
None	PM fails after repair activity	Contact IMS support. Functional Verification and Calibration required after re-repair.
0-yyy	Problem found by the Display Control Processor, non-isolated, section of the PM Main Board.	Contact IMS support.
1-yyy	Problem found by the Data Acquisition Processor isolated, section of the PM Main Board.	Contact IMS support
3-yyy	Problem found by the SpO2 Control Processor on the SCP Board.	Contact IMS support
5-yyy	Problem found by the Main Stream Processor on the MSP Board.	Contact IMS support
yyy	Indicates the specific type of problem	Contact IMS support

Table 4-16. Equipment Alerts and Caution Messages

Message	Condition	Corrective Action
CHECK ACUITY/DATA COMM CONNECTION	Data communication cable internal to the LSTAT is unconnected from the PM	Turn off the PM and then on again. If situation persists, then press the DISABLE button for emergency operation without data logging of PM data. Have the PM serviced as soon as possible.
SIMULATING	INSERV mode activated; simulated patient data is being displayed and saved in trend memory.	Turn off the PM and then on again.

PROGRAM FAULT: SETTINGS LOST, TIME/DAY RESET	The monitor cannot recall the current time and the programmed turn -on settings. This is usually caused by a drained lithium battery inside the PM. The PM can be used, but all settings will be set their factory defaults each time the PM is turned on.	Re-enter settings. If the problem persists, then the PM will require servicing and the battery replaced.

Table 4-17. ECG Messages

Message	Condition	Corrective Action
ECG FAULT	ECG lead fault for four or more leads. Alert window will appear indicating which leads are faulty.	Check ECG lead wires, electrodes and cable.

Table 4-18. Invasive Pressure Messages

Message	Condition	Corrective Action
Px NOT ZEROED (Blood Pressure window)	Appears the first time a transducer is connected to the monitor. It indicates that no zero reference has been established. Pressure waveform displayed, but no pressure waveform scale.	Establish a zero reference.
Px ZEROING (Blood Pressure window)	Appears briefly as the transducer is being zeroed.	Not required.
Px ZEROED (Blood Pressure window)	Zero value accepted. Message will remain for 8 seconds and is replaced by the current pressure values. Pressure waveform will appear.	Not required.
Px ZERO REJECTED (Blood Pressure window)	Unsuccessful attempt to acquire zero reference value.	Press CANCEL to remove message. Transducer or cable may be defective. Check both and re-attempt.
Px CANCELLED (Blood Pressure window)	appears after the CANCEL button is pressed and will remain for 8 seconds.	Not required.
P1 FAULT (P2 FAULT) (Time of Day window)	Transducer fault detected.	Replace Transducer
TRANSDUCER NOT DETECTED (Alert and Time of Day window)	Transducer connection broken.	Check transducer and transducer connections. Replace/reconnect as necessary.
TRANSDUCER SHORTED (Alert and Time of Day window)	Transducer short	Replace transducer
INCOMPATIBLE TRANSDUCER (Alert and Time of Day window)	HP1290A invasive transducer connected in and not compatible with this option.	Replace transducer with approved transducer.

Table 4-19. Cuff Messages (Equipment Alert window and Cuff window)

Message	Condition	Corrective Action
CUFF FAULT: LOW BATTERY, CUFF DISABLED	Electrical power subsystem problem.	Switch to external power if on LSTAT batteries. Ensure Main Power Switch on and circuit breakers not tripped.

Message	Condition	Corrective Action
CUFF FAULT: CALIBRATION ERROR, CUFF DISABLED	Cuff channel cannot properly calibrate itself and must be disabled. Cuff channel cannot be used.	Press the Disable button. Contact IMS support.
CUFF FAULT: MEASUREMENT TIME OUT	A valid cuff measurement could not be determined in 3 minutes.	Attempt the measurement again.
CUFF FAULT: EXCESSIVE ARTIFACT	Too much patient motion, patient arrhythmia or sources of external movement.	Attempt the measurement again.
CUFF FAULT: NO PULSES DETECTED	Cuff may not be on or not on a patient properly.	Re-position/reapply cuff. If signal persists, replace cuff.
CUFF FAULT: NO CUFF	Detected pressure did not rise sufficiently during inflation.	Ensure cuff connection tight and take measurement again. If message persists replace cuff.
CUFF FAULT: NO VALID BLOOD PRESSURE FOUND	Measurement data acquired cannot be processed.	Check for patient motion, arrhythmia or outside environmental influences such as transport vibration, which can cause the message. Take measurement again.
CUFF FAULT: KINKED HOSE, CHECK HOSE	Cuff could not be properly inflated.	Check for kinked hose between monitor and patient.
CUFF FAULT: BLOCKED VENT	Cuff pressure cannot be vented to the atmosphere	Inspect vent hole for visible blockage and clear.
CUFF FAULT: AIR LEAK CHECK HOSE	Cuff does not inflate properly.	Check hose and cuff for leaks (around O-rings in hose) and replace as necessary.
CUFF FAULT: WEAK PULSES, CAN'T FIND SYS/DIAS	Not enough pulses to determine the systolic or diastolic pressures, but a mean pressure is available.	Reapply cuff after squeezing as much air out as possible. Take another measurement. If message persists replace cuff.
CUFF FAULT: OVER PRESSURE CONDITION, CHECK HOSE	High cuff pressure caused by patient motion	Check hose, press Disable button, and take pressure again. If message persists replace hose or cuff as necessary.
CUFF FAULT: OVER PRESSURE CONDITION, CYCLE POWER	Cuff channel has been disabled	Power-off and then power-on PM and start measurements again. If message persists contact IMS support.
CALIBRATING	Cuff channel running an internal calibration	None
DISABLED, CAL ERROR	See CUFF FAULT: CALIBRATION ERROR, CUFF DISABLED	Same corrective action for described condition.
DISABLED, LOW BATT	See CUFF FAULT: LOW BATTERY, CUFF DISABLED	Same corrective action for described condition.

Table 4-20. Temperature Messages

Message	Condition	Corrective Action
PROBE NOT DETECTED	Temperature has been successfully measured and a probe is disconnected.	Reconnect the probe and press the main menu key to acknowledge the alert.
PROBE SHORT OR OUT OF RANGE	Temperature being measured may be beyond the range of the probe or the range of the PM.	Reapply probe. If condition persists replace probe.
CALIBRATION ERROR, TEMP DISABLED	Temperature circuitry to all temperature channels is out of calibration	Temperature channel cannot be used. Do not use temperature channel or contact IMS support.

SpO_2 messages can appear in the equipment alert window (SpO_2 equipment alert), the SpO_2 numeric window, or alternate with the time of day (SpO_2 caution messages).

Table 4-21. SpO_2 Messages

Message	Condition	Corrective Action
NO SENSOR DETECTED	A probe has been disconnected from the monitor after being plugged in for a few seconds	Pressing any key deactivates the alert, removes the SpO_2 plethysmograph, and deactivates the channel.(If an SpO_2 sensor is subsequently connected to the PM, the channel becomes active and performs its self-calibration)
SEARCH	Displayed in numeric window after the Pulse Oximetry sensor is first connected to the monitor.	During this search time, the SpO_2 channel tries to detect blood pulsing through the measurement site. Once the measurement has been established, the oxygen saturation value is displayed in the numeric window.

Equipment messages regarding the CO_2 can appear on the display in equipment alert window and in numeric zones.

Table 4-22. CO_2 Messages

Message	Condition	Corrective Action
(No Message)	Apnea Alarm. BR numeric goes to zero	Alarm is canceled when patient takes a breath. CO_2 waveform will be displayed
ALTIMETER FAILURE, RANGE	The PM is being operated at an altitude of the CO_2 operating range. The range is -2,000 to 15,000 feet.	Returning to within the operating range will automatically cancel the message and restore operation.
ALTIMETER FAILURE, RATE	The altimeter has detected an altitude change rate greater than 100 mm/minute. The altitude change rate must be less than 100 mm/minute.	When altitude change rate within range, simply disconnect and reconnect the CO_2 sensor to the PM.
DEGRADED WAVEFORM **(UNCAL also appears in CO_2 numerics area. CO_2 waveform displayed without range values)**	CO_2 mainstream adapter is obstructed or the CO_2 sensor has failed.	Remove and replace the adapter or the sensor or both as necessary.
LACK OF WAVEFORM, SENSOR DISABLED	Adapter is obstructed or CO_2 sensor has failed	Replace the adapter if it is obstructed. Disconnect and reconnect the sensor.
LOW BATTERY, HEATER DISABLED **(UNCAL also appears in the numerics area)**	Battery voltage less than 7.3 volts. The CO2 waveform is displayed without range values.	LSTAT battery needs to be recharged. Switch to external electrical power.
NO SENSOR DETECTED **(The breath rate numeric area displays SRCH)**	CO_2 sensor has been disconnected from the PM after providing CO_2 values.	Check the sensor connection. Disconnect and reconnect the sensor to the PM if necessary. If condition persists, replace the sensor.
NON-PROTOCOL SENSOR **(UNCAL also appears in CO_2 numerics area. CO_2 waveform displayed without range values)**	A CO_2 sensor has been connected to the PM that does not match PM specifications.	Remove the sensor and replace it with an approved sensor.
SENSOR FAILURE, E2PROM	Sensor defective or out of calibration Failed sensor	Remove and replace the sensor

Message	Condition	Corrective Action
SENSOR FAILURE, HEATER	Sensor temperature control circuit or CO_2 circuitry has failed.	Remove and replace sensor..
SENSOR FAILURE, MOTOR DRIVE	Sensor motor drive in sensor head has failed.	Remove and replace sensor.
SENSOR TEMPERATURE TOO HIGH	Sensor temperature is too high. The operating range is 10° to 46° C.	Allow to cool down. When ambient temperature is returned within range, message will be removed automatically and operation restored.
WARM UP or WARM **(appears in CO_2 numerics area)**	Sensor heater is warming up	Wait 20-30 seconds for the sensor to heat up. Values should appear in the numerics area once the sensor is warm.

CHAPTER 5 SUCTION

5.1 Intended Use and Limitations

Do not operate at temperatures below -20°C or above 49°C.

5.2 Alarms and Indicators

5.3 Equipment

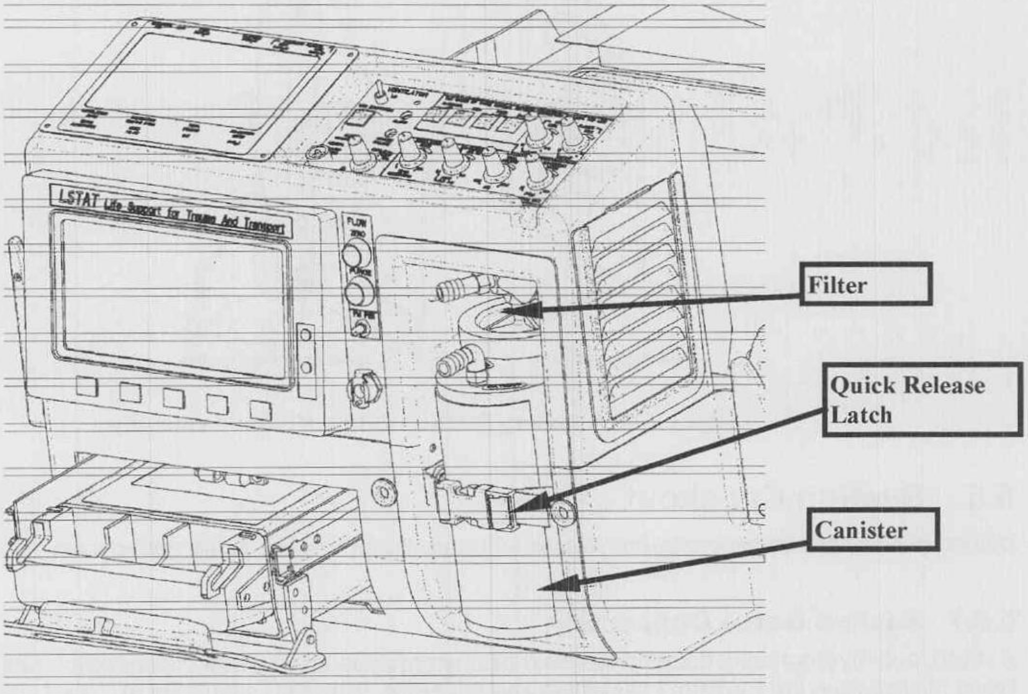

LSTAT Life Support for Trauma And Transport
Filter
Quick Release Latch
Canister

Figure 5-1. Suction Bottle and Fittings

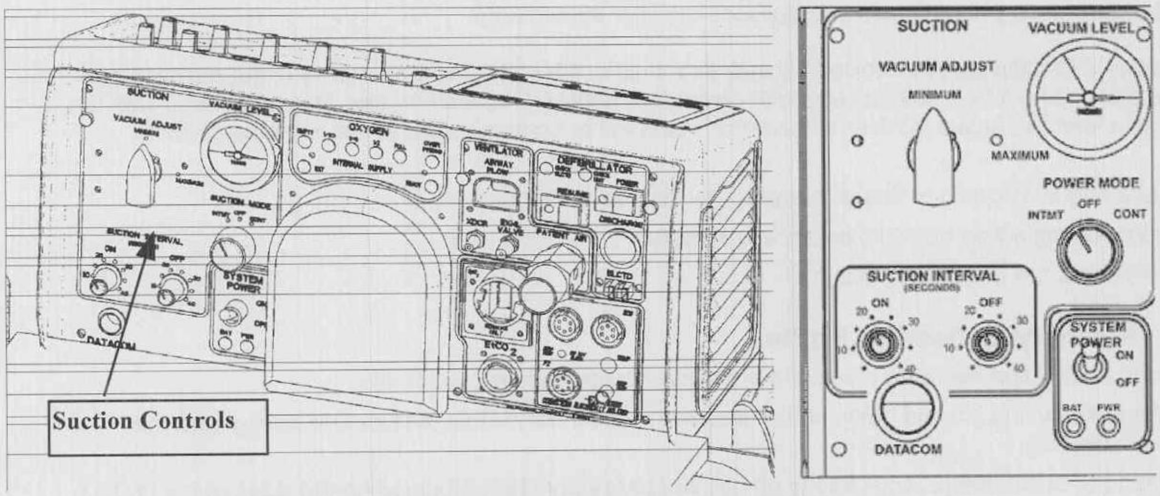

SUCTION
VACUUM LEVEL
VACUUM ADJUST
MINIMUM
MAXIMUM
POWER MODE
OFF
INTMT
CONT
SUCTION INTERVAL
(SECONDS)
ON
OFF
20
30
10
40
SYSTEM POWER
ON
OFF
BAT
PWR
DATACOM
OXYGEN
VENTILATOR
DEFIBRILLATOR
Suction Controls

Figure 5-2. Suction Controls

5.4 Accessories

Use the accessories listed in Appendix D and where called out in this section.

5.4.1 Auxiliary Collection Bottle

The Auxiliary Collection System includes the bottle holder assembly (Figure 5-3), and an auxiliary bottle with fittings and tubing.

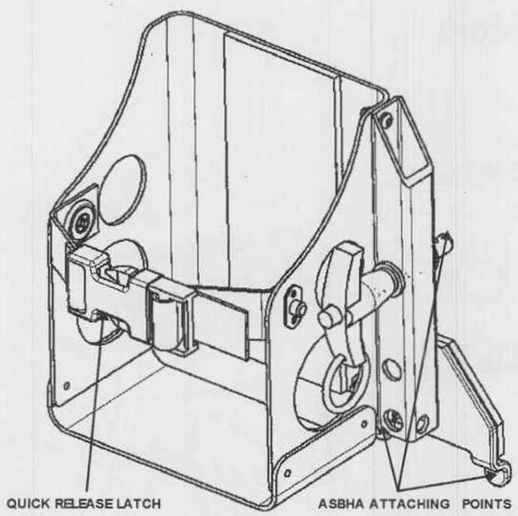


Figure 5-3. Auxiliary Suction Bottle Holder Assembly

5.5 Suction Checkout

Before operating the suction system conduct the following checks to insure proper performance.

5.5.1 Suction Bottle Connection

A disposable hydrophobic, bacteria overflow filter is provided for use with the collection bottle. This filter connects between the Vacuum Inlet Fitting and the bottle. This filter should be replaced when discoloration of its membrane occurs, the membrane contacts aspirate, or following 150 cumulative hours of use. This filter is designed to retain bacteria that would otherwise be exhausted into the immediate vicinity. The filter's retention of aerosolized aspirate will create more resistance to airflow. It is important that the operator be aware of this and replaces the filter accordingly.

Disposable collection bottles traditionally include a built-in filter and may be used. It is not necessary to use the disposable filter in conjunction with disposable bottles. Reusable bottles should be used with the disposable filter to prevent inadvertent overflow, damage or contamination of the pump mechanism.

1. Insure that all hoses and fittings are properly connected (Figure 5-4).
2. Verify that collection bottle lid is properly secured.
3. Verify there are no kinks in tubing.

5.5.2 Auxiliary Collection Bottle

An auxiliary collection bottle may be used in series with the main suction bottle.

1. Take the auxiliary suction bottle holder assembly, secondary bottle, fittings and tubing from the accessory bag.
2. Attach the bottle holder assembly to one of the four IV pole holes located on the sides of the LSTAT.
3. Install the auxiliary bottle in the bottle holder assembly and secure with the quick release latch (Figure 5-1).

4. Attach appropriate patient suction equipment to the auxiliary bottle.
5. Connect the auxiliary bottle to the main suction bottle as depicted in Figure 5-4.

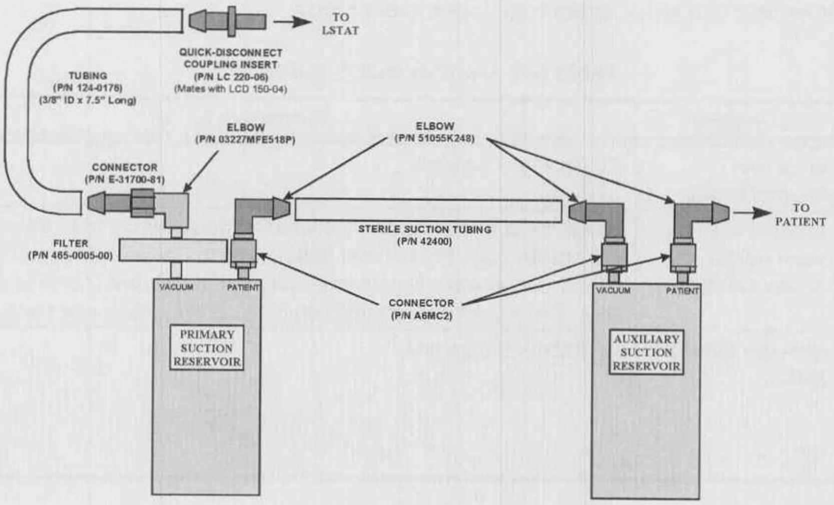

TO LSTAT
QUICK-DISCONNECT COUPLING INSERT (P/N LC 220-06) (Mates with LCD 150-04)
TUBING (P/N 124-0176) (3/8" ID x 7.5" Long)
ELBOW (P/N 03227MFE518P)
ELBOW (P/N 51055K248)
CONNECTOR (P/N E-31700-81)
TO PATIENT
STERILE SUCTION TUBING (P/N 42400)
FILTER (P/N 465-0005-00)
VACUUM
PATIENT
CONNECTOR (P/N A6MC2)
VACUUM
PATIENT
PRIMARY SUCTION RESERVOIR
AUXILIARY SUCTION RESERVOIR

Figure 5-4. Suction Bottle and Auxiliary Bottle Connection

5.5.3 Suction Pre-Operation

1. Toggle *SYSTEM POWER* to ON.
2. On the SUCTION Panel (Figure 5-2), turn the *POWER MODE* knob to INTMT to verify intermittent operation.
3. Listen to verify suction pump begins operation.
4. Turn the *POWER MODE* knob to CONT to verify continuous operation.
5. Listen to verify suction pump begins operation.
6. Test the *VACUUM ADJUST* for correct operation at various vacuum settings.

5.6 Suction Operation

1. Turn the *POWER MODE* knob from *OFF* to the *CONT* or *INTMT* position, as desired. The internal pump should begin operation.

The *VACUUM ADJUST* works in conjunction with the *VACUUM LEVEL* gauge. Vacuum levels may be selected by rotating the *VACUUM ADJUST* knob clockwise to increase vacuum or counterclockwise to decrease vacuum.

2. Turn the *VACUUM ADJUST* knob to the maximum desired vacuum level while pinching and holding the vacuum tubing going to the patient.

Deliverable vacuum levels will not exceed the preset maximum level. Adjusted and delivered vacuum levels are displayed on the *VACUUM LEVEL*.

For Gastrointestinal drainage:

3. Turn the *POWER MODE* knob to *INTMT*.
4. Turn the *SUCTION INTERVAL ON TIME* knob to the desired length of time.
5. Turn the *SUCTION INTERVAL OFF TIME* knob to determine how long before the next intermittent cycle will begin.
6. Turn *POWER MODE* knob to *OFF* to turn off suction.

5.7 Suction Diagnostics

Suction diagnostics consist of observed irregularities in the Continuous and Intermittent modes of operation. Table 5-1 defines the conditions and corrective actions for Continuous Mode and Table 5-2 defines the conditions and corrective actions for Intermittent Mode.

Table 5-1. Continuous Suction

Indication	Condition	Corrective Action
LSTAT on, pump will not function.	No power-internal failure	Contact IMS support.
No vacuum/ weak vacuum	Internal failure, worn hoses, or an occluded filter	Check hose and hose connections for cracks or crimps. Ensure canister lids are sealed tight. Press reset button next to Portable Clinical Analyzer in foot fairing. Ensure the filter is not occluded. If it is, then remove and replace the filter. See Figure 5-4. If condition persists remove contact IMS support.
Vacuum gauge registers "0" but there is vacuum at the canister outlet.	Vacuum Gauge failure.	Contact IMS support.

Table 5-2. Intermittent Suction

Indication	Condition	Corrective Action
LSTAT on, Pump does not function.	No Power	Check if LSTAT powered up and circuit breakers not tripped and recycle power to LSTAT. Power up Suction. If condition persists, contact IMS support.
Poor operation	Internal failure	Contact IMS support.
On or Off cycle does not end.	Internal failure	Cease suction, power down LSTAT, contact IMS support.
Vacuum gauge registers "0" but there is vacuum at the canister outlet.	Vacuum Gauge failure.	Contact IMS support.

5.8 Turn Around and Servicing

When no longer required, perform necessary turnaround and servicing as contained in Section 12.2.6 to replace contaminated tubing, filters, etc.

CHAPTER 6 DEFIBRILLATION

6.1 Intended Use and Limitations

WARNING

POSSIBLE EXPLOSION HAZARD IF USED IN THE PRESENCE OF CONCENTRATED OXYGEN.

DEFIBRILLATION CURRENT CAN CAUSE OPERATOR INJURY. DO NOT TOUCH THE PATIENT DURING DEFIBRILLATION.

DO NOT TOUCH METAL OBJECTS IN CONTACT WITH THE PATIENT DURING DEFIBRILLATION.

DISCONNECT OTHER ELECTRICAL EQUIPMENT FROM THE PATIENT BEFORE DEFIBRILLATING. Physiological ECG monitoring equipment, if attached, may remain in place.

SUDDEN POWER LOSSES TO THE LSTAT MAY CAUSE DEFIBRILLATOR POWER LOSS. TO AVOID POSSIBLE HAZARD OF CHARGED CAPACITORS, THE DEFIBRILLATOR POWER MUST BE CYCLED. When LSTAT power is restored, turn the defibrillator ON. Wait at least 10 seconds and then turn the defibrillator OFF. This will discharge the capacitors.

Do not operate at temperatures below 0°C or above 50°C.

The defibrillator produces a hazardous electrical output, use only by qualified personnel.

The defibrillator is automated, including voice-prompted operation, for emergency treatment of victims of a traumatic cardiac arrest who weigh more than 40 kg (90 lb.). **Voice prompting occurs automatically at appropriate intervals whenever the defibrillator power is on**. Activate the defibrillator and apply the electrodes **ONLY** if the patient is **unconscious**, has **no pulse** and **no respiration.**

CAUTION

Radio Frequency (RF) interference can cause improper operation. In accordance with IEC Standard 801.3, a distance of 2 meters (6 feet) between RF devices and the Defibrillator is recommended.

Using the Defibrillator when transporting the patient can cause improper diagnosis. Use the Defibrillator only when the patient is not being moved and/or the vehicle is stationary.

Improper maintenance can cause the defibrillator not to function. Maintain the defibrillator as described in this manual.

6.2 Alarms and Indicators

6.3 Equipment

6.3.1 Controls and Indicators

The defibrillator operator controls are illustrated in Figure 6-1.

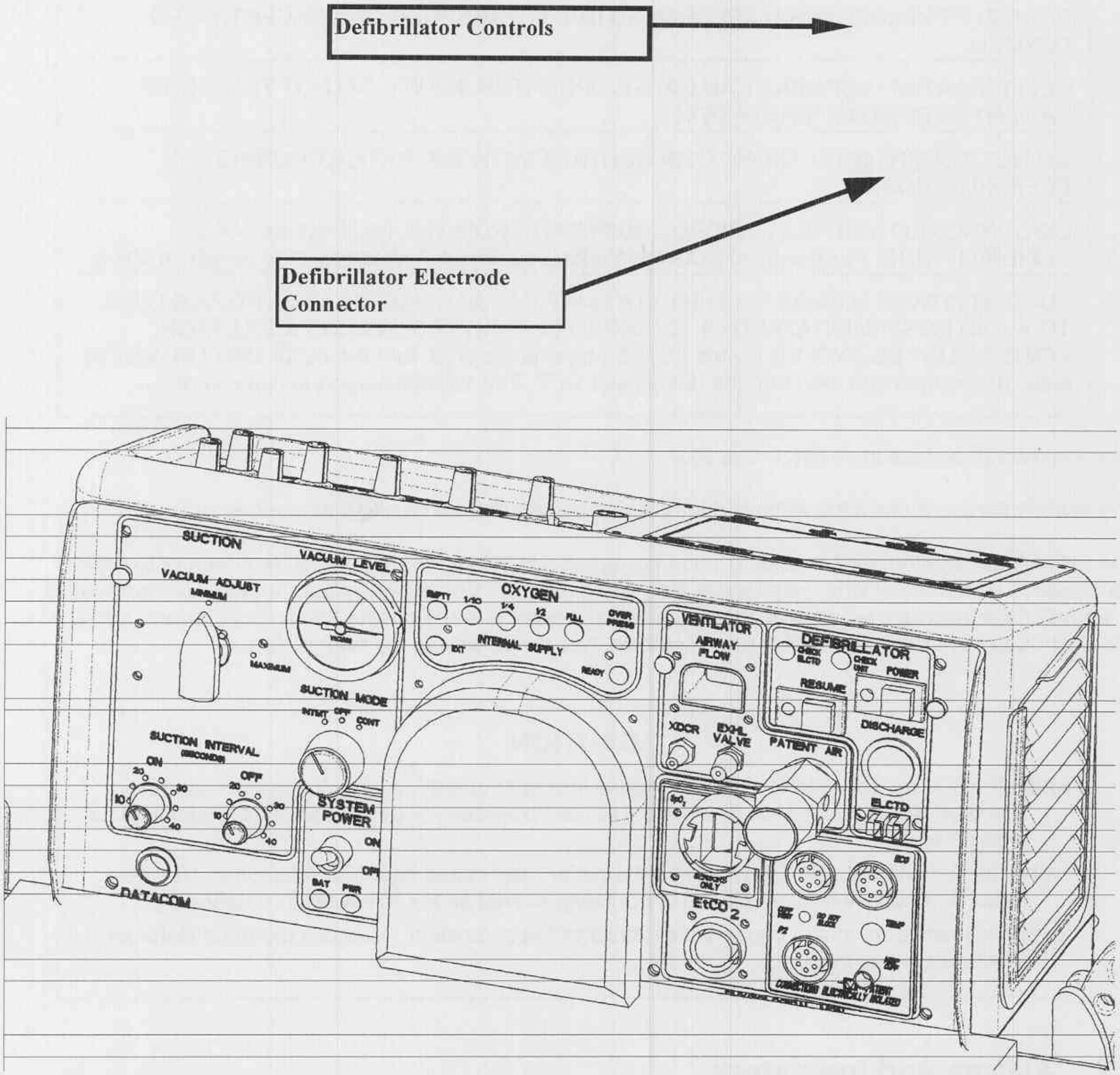

Defibrillator Controls
Defibrillator Electrode Connector
SUCTION
VACUUM ADJUST
MINIMUM
MAXIMUM
VACUUM LEVEL
OXYGEN
EMPTY
1/10
1/4
1/2
FULL
OVER PRESS
EXT
INTERNAL SUPPLY
READY
SUCTION MODE
INTMT
OFF
CONT
SUCTION INTERVAL
(SECONDS)
ON
OFF
SYSTEM POWER
ON
OFF
BAT
PWR
DATACOM
VENTILATOR
AIRWAY FLOW
XDCR
EXHL VALVE
PATIENT AIR
DEFIBRILLATOR
CHECK ELCTD
CHECK UNIT
POWER
RESUME
DISCHARGE
ELCTD
ECG
EtCO2
TEMP

Figure 6-1. **Defibrillator Control Panel**

6.4 Accessories

Utilize the accessories listed in Appendix D and where called in this section.

6.4.1 Electrodes

Use only Defibrillator Model 9010 electrodes with the defibrillator. Improper electrodes will cause a maintenance alert.

Defibrillator Electrodes have a one-year shelf life. Check date on packet before using. If expired, obtain an unexpired replacement set.

6.5 Defibrillator Operation

6.5.1 Electrode Placement and Connection

> NOTE
>
> The electrodes must be attached to the Defibrillator all times or an electrode fault may occur at self-test. Do not open sealed electrode package until prompted to place electrodes on patient.

1. Take a sealed defibrillator electrode set from the accessory bag.
2. Connect sealed electrode package to electrode connector on the defibrillator panel (Figure 6-1).
3. Toggle *SYSTEM POWER* to *ON*.
4. Press the defibrillator *POWER* button to turn on the Defibrillator.
5. Wait approximately 30 seconds for the system to complete a self-test.
6. Follow defibrillator prompts.

If the self-test is successful the defibrillator will prompt to PRESS RESUME BUTTON AND CONTINUE. If a fault is found during self-test a beep will sound. Check the LED's and perform the required actions.

7. Press the *RESUME* button.
8. The defibrillator will prompt to PLACE ELECTRODES. Open the electrode package.
9. Place the electrodes on the patient's chest as shown in Figure 6-2.

> NOTE
>
> If the electrodes are not connected properly the defibrillator will prompt to **"CHECK ELECTRODES"**. Check the electrodes for proper connection and then for placement on the patient. If the voice prompt of **"CHECK ELECTRODES"** persists, then ensure that the electrodes are warm enough. (Electrode impedance may occur at temperatures below 0° Centigrade).

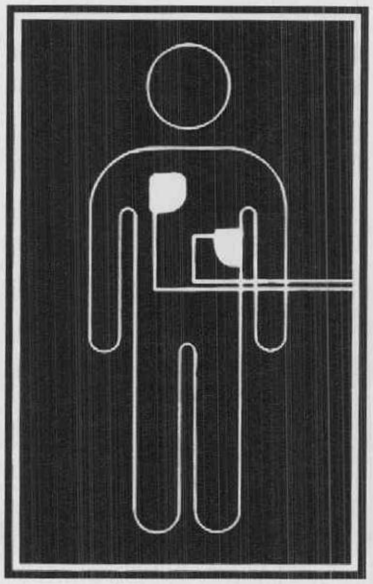


Figure 6-2. Defibrillator Electrode Placement

6.5.2 Semi-Automated Defibrillation

1. After electrodes are properly placed on the patient, the defibrillator voice will prompt: **DO NOT TOUCH PATIENT, ANALYZING RHYTHM**. Do not touch the patient at this time.
2. If the defibrillator detects a shockable cardiac rhythm, the defibrillator will charge automatically and the voice will prompt: **CHARGING.** When the charge is ready, the *DISCHARGE* button will flash and the voice will prompt will: **STAND CLEAR. PUSH FLASHING BUTTON TO RESCUE**. Push the *DISCHARGE* button to deliver the first shock of 200 Joules (J).

If the flashing *DISCHARGE* button is not pressed within 30 seconds, the charge will be internally dissipated.

3. After a 5 second pause, the defibrillator will analyze the patient's cardiac rhythm again. The voice will prompt: **DO NOT TOUCH PATIENT, ANALYZING RHYTHM.** Do not touch the patient at this time.
4. If the patient still has a shockable cardiac rhythm the defibrillator will charge automatically and the voice will prompt: **CHARGING**. When the charge is ready the *DISCHARGE* button will flash and the voice will prompt: **STAND CLEAR. PUSH THE FLASHING BUTTON TO RESCUE**. Push the *DISCHARGE* button to deliver the second shock of 300 J.
5. After a 5 second pause, the defibrillator will analyze the patient's cardiac rhythm again. The voice will prompt: **DO NOT TOUCH PATIENT, ANALYZING RHYTHM.** Do not touch the patient at this time.

NOTE

If the patient no longer has a shockable cardiac rhythm the voice prompt will advise: **"CHECK PULSE. IF NO PULSE, GIVE CPR".** Proceed with CPR for 1 minute if there is no pulse. After 1 minute the voice prompt will advise: **"DO NOT TOUCH PATIENT. ANALYZING RHYTHM"**. This sequence will repeat until the patient's rhythm is shockable.

6. If the patient still has a shockable cardiac rhythm the defibrillator will charge automatically and the voice will prompt: **CHARGING**. When the charge is ready the *DISCHARGE* button will flash and the voice will prompt: **STAND CLEAR. PUSH THE FLASHING BUTTON TO RESCUE**. Push the *DISCHARGE* button to deliver the third shock of 360 J.
7. After the third shock the voice will prompt: **CHECK PULSE. IF NO PULSE, GIVE CPR**. Proceed with CPR for 1 minute if there is no pulse.

After 1 minute the voice will prompt: **DO NOT TOUCH PATIENT. ANALYZING RHYTHM**. The defibrillator will automatically repeat the sequence of 3 shocks followed by one minute of CPR until a shockable rhythm is no longer detected. All subsequent shocks will be administered at 360 J.

8. Continue treatment until a pulse is detected or it is medically determined that defibrillation is no longer required.
9. When defibrillation is no longer required, press the *POWER* button to disarm and turn off the defibrillator.
10. Remove the defibrillator electrodes from patient.
11. Disconnect the electrodes from the defibrillator panel.
12. Discard the electrodes when no longer required.

6.6 Defibrillator Diagnostics

The Defibrillator Unit has an internal diagnostic capability. Failures are indicated with lights on the Head Fairing (Figure 6-1). Table 6-1 defines the indications, conditions and corrective action(s).

Table 6-1. Defibrillator Diagnostics

Indication	Condition	Corrective Action
No POWER light and no voice prompt	No POWER	Check LSTAT for power up and circuit breakers that have not tripped, and recycle power to LSTAT and Defibrillator. If condition persists, contact IMS support.
No POWER light, but voice prompt	POWER LED burnt out	Follow voice prompt
Unit chirps	Self test fault.	Turn Defibrillator on if not already powered on. Check the LED lights. If the CHECK ELCTD LED is lit, then replace the electrodes. If the CHECK UNIT LED is lit then the Defibrillator must be repaired. contact IMS support
CHECK ELCTD light on NOTE: This failure only exhibits itself at Defibrillator Power On.	Electrodes are not connected at the Head Fairing, are not placed on the patient properly, or the adhesive gel on the electrodes has dried out.	Connect electrodes to the Head Fairing, check electrode connection, check electrode placement on patient and place according to defibrillator placard, or replace with a new set of electrodes.
CHECK UNIT light on	Internal failure	Contact IMS support.
POWER light on, CHECK UNIT light not on, No voice prompt	Speaker malfunction	Discontinue use of Defibrillator. NOTE: The Defibrillator may be used ONLY if the operator is thoroughly familiar with Defibrillator operations and has read and understands the sequence of operation contained in the LSTAT User Manual.
No RESUME light but voice prompt	RESUME LED burnt out	Follow voice prompt.

CHAPTER 7 FLUID/DRUG INFUSION

7.1 Intended Use and Limitations

Do not operate at temperatures below 10°C or above 40°C.

7.1.1 Epidural Administration

The infusion pump can be used for epidural administration of anesthetic and analgesic drugs. This application is only appropriate when using anesthetic and analgesic drugs labeled for continuous epidural administration and catheters intended specifically for epidural use. Use only IVAC 28 or 25 series set with a "Y" connector or injection port, for epidural infusions.

Epidural administration of anesthetic drugs

Use indwelling catheters specifically indicated for short-term (96 hours or less) anesthetic epidural drug delivery.

Epidural administration of analgesic drugs

Use indwelling catheters specifically indicated for either short-term or long-term analgesic epidural drug delivery.

7.2 Alarms and Indicators

7.2.1 Access Alarm information

ALARM is displayed in the affected channel status line. Alarm condition is displayed on the Standard Display of the affected channel.

1. Press *A, B* or *C* for the affected channel. An alarm information page will be displayed for the affected channel.

7.2.2 KVO (Keep Vein Open) Status

The green light on the channel key remains on.

The red light on the channel key flashes.

A two toned advisory sounds.

7.3 Equipment

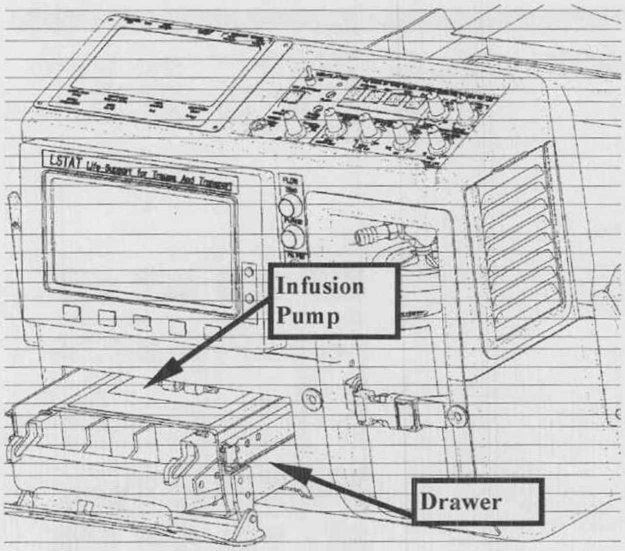

LSTAT Life Support for Trauma And Transport
Infusion Pump
Drawer

Figure 7-1. Infusion Pump in Drawer

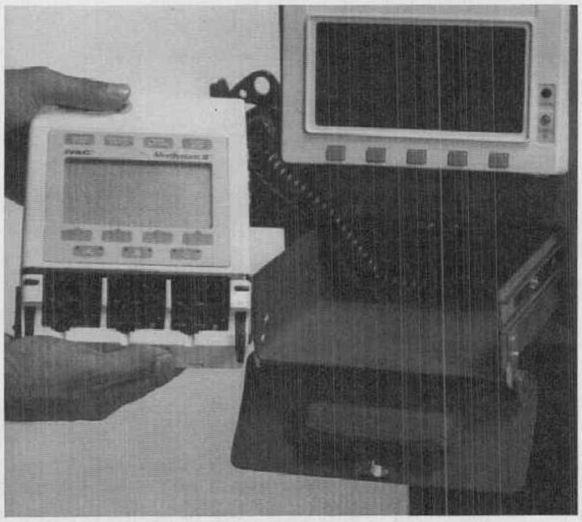
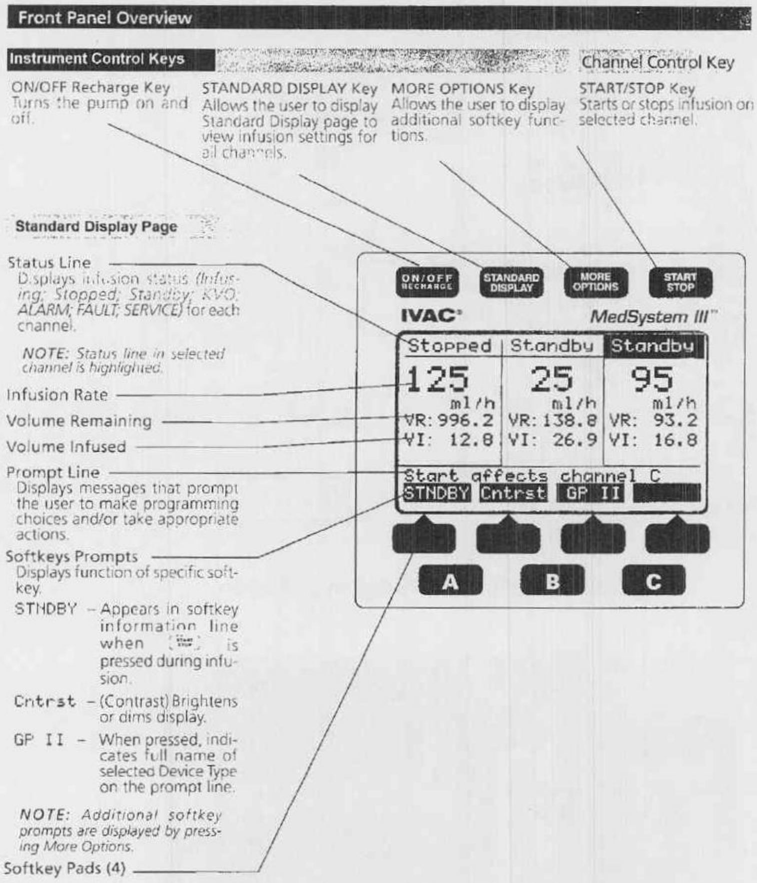


Figure 7-2. Infusion Pump

7.3.1 Controls and Displays



Front Panel Overview

Instrument Control Keys

ON/OFF Recharge Key
Turns the pump on and off.

STANDARD DISPLAY Key
Allows the user to display Standard Display page to view infusion settings for all channels.

MORE OPTIONS Key
Allows the user to display additional softkey functions.

Channel Control Key

START/STOP Key
Starts or stops infusion on selected channel.

Standard Display Page

Status Line
Displays infusion status (*Infusing; Stopped; Standby; KVO; ALARM; FAULT; SERVICE*) for each channel.

NOTE: Status line in selected channel is highlighted.

Infusion Rate

Volume Remaining

Volume Infused

Prompt Line
Displays messages that prompt the user to make programming choices and/or take appropriate actions.

Softkeys Prompts
Displays function of specific softkey.

STNDBY – Appears in softkey information line when [⌸] is pressed during infusion.

Cntrst – (Contrast) Brightens or dims display.

GP II – When pressed, indicates full name of selected Device Type on the prompt line.

NOTE: Additional softkey prompts are displayed by pressing More Options.

Softkey Pads (4)

Figure 7-3. Infusion Pump Controls and Display

7.4 Accessories

CAUTION

Using the Infusion Pump on its own battery power without LSTAT power will not allow data to be captured by the Display/Data Logging Subsystem (DDLS) and will draw down the battery.

Use the accessories listed in Appendix D where called out in this section.

Use only IVAC 28 and 25 Series Administration Sets. The use of other sets will cause improper pump operation.

7.5 Infusion Setup

7.5.1 Infusion Pump Check-out

1. Open the infusion pump drawer (Figure 7-1).
2. Visually check the pump for any obvious discrepancies that in the judgment of the operator would preclude operation.

WARNING

IF A PUMP IS DROPPED OR SEVERELY JARRED, IT SHOULD BE IMMEDIATELY TAKEN OUT OF SERVICE AND INSPECTED BY QUALIFIED SERVICE PERSONNEL TO ENSURE PROPER FUNCTION PRIOR TO USE.

3. Press the *ON/OFF RECHARGE* button on the display (Figure 7-3).

The Instrument Information page is momentarily displayed.

4. Continue to hold down the *ON/OFF RECHARGE* button to keep the Instrument Information page on the display.

The standard display page (Figure 7-3) will be shown when the *ON/OFF RECHARGE* button is released.

5. Verify the display is complete and not blurred when operating.
6. Press the **Cntrst** softkey to brighten or dim the display as necessary.

To activate additional Standard Display prompts:

7. Press the *MORE OPTIONS* button. **TotVol**, **Device**, **Config**, and **Note** options will be displayed.
8. Press the *MORE OPTIONS* button again. **Batlog** and **DemoWd** options will be displayed.

7.5.2 Intravenous Pole and Fluid Setup

1. Take the intravenous (IV) poles from the accessory bag.
2. Insert IV pole into one of the four slots on the sides of LSTAT.
3. Extend IV poles and lock into place.
4. Prepare the IV solution.
5. Hang bags according to infusion requirements.
6. Take the rotating pole clamp from the accessory bag, if required.
7. Attach the rotating pole to the infusion pump
8. Attach the clamp to rigid support.

NOTE

Use the Hot Sack if warming the IV fluid is necessary.

7.5.3 Prepare the Administration Set

1. Take an Administration Set cassette from the accessory bag.
2. Inspect Administration Set. If damaged replace.
3. Ensure the cassette slide clamp is pushed in completely so tubing is not occluded (Figure 7-4).
4. Invert the cassette so tubing is up.
5. Slowly open the regulating clamp and establish fluid flow to fully prime the set.
6. Gently tap the cassette and the "Y" sites as necessary to remove all air.
7. Gently massage the pressure dome to ensure no air bubbles are trapped.

WARNING

DO NOT USE THE SET IF DAMAGED.

IT IS IMPORTANT TO PRIME THE SET PROPERLY TO ELIMINATE AIR BUBBLES.

AN OPEN REGULATING CLAMP AND SLIDE CLAMP CAN CAUSE A FREE-FLOW CONDITION AND MAY RESULT IN SERIOUS INJURY TO THE PATIENT.

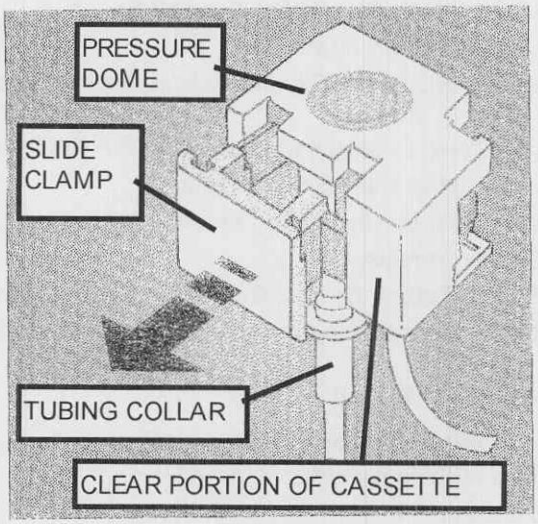


Figure 7-4. Preparing the Administration Set

7.5.4 Load the Administration Set

1. Close the regulating clamp before inserting and removing the cassette to reduce the risk of free flow.
2. With tubing down, use a 45° upward motion to insert cassette into channel (Figure 7-5).
3. Push on clear portion of cassette until completely seated.
4. Push inside clamp flush with entire cassette.
5. Pull down gently on tubing collar.
6. Press with thumb to seat tubing collar in recess beneath cassette (Figure 7-6).

Three beeps sound when inserted properly.

WARNING

DO NOT INSERT A CASSETTE INTO A CHANNEL WITH A SERVICE STATUS.

REMOVE ANY CASSETTE FROM THE CHANNEL(S) REQUIRING SERVICE.

ENSURE THE CASSETTE IS PROPERLY INSTALLED BEFORE STARTING INFUSIONS.

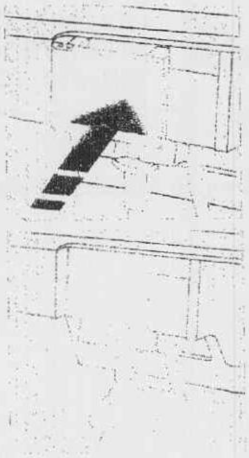


Figure 7-5. Loading the Administration Set

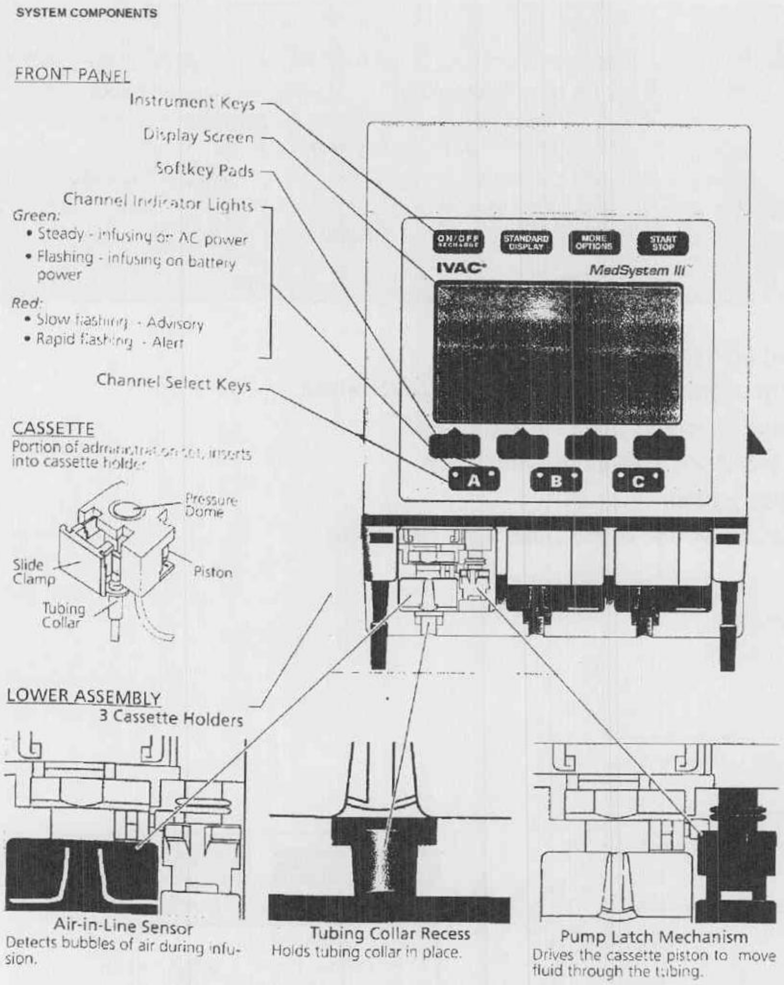

SYSTEM COMPONENTS
FRONT PANEL
Instrument Keys
Display Screen
Softkey Pads
Channel Indicator Lights
Green:
• Steady - infusing on AC power
• Flashing - infusing on battery power
Red:
• Slow flashing - Advisory
• Rapid flashing - Alert
Channel Select Keys
CASSETTE
Portion of administration set, inserts into cassette holder
Pressure Dome
Slide Clamp
Piston
Tubing Collar
ON/OFF RECHARGE
STANDARD DISPLAY
MORE OPTIONS
START STOP
IVAC
MedSystem III
A
B
C
LOWER ASSEMBLY
3 Cassette Holders
Air-in-Line Sensor
Detects bubbles of air during infusion.
Tubing Collar Recess
Holds tubing collar in place.
Pump Latch Mechanism
Drives the cassette piston to move fluid through the tubing.

Figure 7-6. Infusion Pump Lower Assembly

7.6 Primary Infusion

1. Press *A, B, or C* buttons to select the channel to program. The Programming Page for the selected channel will be displayed (Figure 7-7).
2. Press the **Select** button to choose the value to change.
3. Press **↑**,**↓**, **Fast↑**, or **Fast↓** to increase or decrease the value selected.
4. Press the *MORE OPTIONS* button to recall a previous value after a new value is introduced but not entered. The Recall soft key will appear.
5. Press the **Recall** button. The number will return to its previous value.
6. Press **Enter** to accept new value.

Highlight remains flashing until *Enter* is pressed. If *Enter* is not pressed, the Entry Incomplete advisory will sound. Highlight moves to next programmable value if channel status is **Stopped** or on **Standby.** If **Infusing,** highlight remains on selected value.

7. Press the *START STOP* button and infusion will start or stop immediately, unless the channel's programming is incomplete, or if an advisory, alarm, or fault condition exists on selected channel.

NOTE

It is normal for intravenous infusion devices to produce non-hazardous currents when infusing electrolytes. These currents vary at a rate proportional to the infusion device flow rate. When the ECG monitoring system is not functioning under optimal conditions, these currents may appear as artifacts, simulating actual ECG readings. To determine if the ECG abnormalities are caused by patient condition or the ECG equipment, place the infusion device on hold. If the ECG readings become normal, the ECG equipment requires attention. Proper setup of the ECG equipment should eliminate these artifacts. Reference the appropriate ECG monitoring system documentation for instructions on setup and maintenance.

To activate additional programming options:

1. From the programming page, press the *MORE OPTIONS* button.
2. Press the **2°Sec** display to access the secondary page.
3. Press **CalcOn** to access Dose Rate Calculation page.
4. Press *MORE OPTIONS* button.
5. Press **CalcOff** to discontinue use of the Dose Rate Calculator.

Programming Page

Selected channel is indicated by the letter displayed at the beginning of the first five lines.

Status Line
Displays infusion status for selected channel.

Infusion Rate

Volume Remaining

Time Remaining

Volume Infused

Date/Time
Displays when volume infused was last cleared and infusion began.

Prompt Line
Displays messages that prompt the user to make programming choices and/or take appropriate action.

Soft Key Prompts
Displays function of specific softkey.

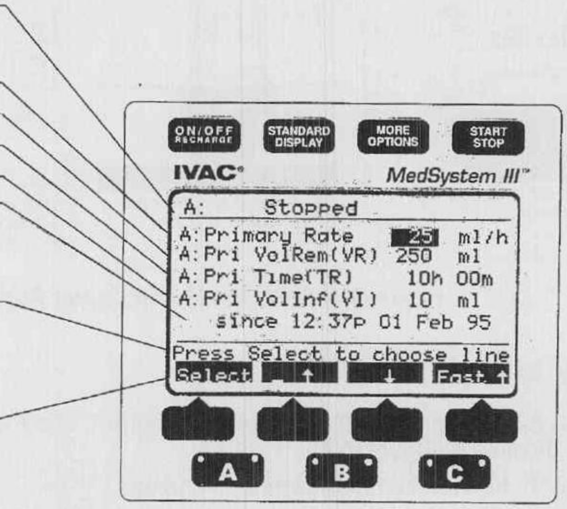
`Select` – Moves highlight bar through the programmable infusion parameters.

↑ – Increases highlighted value.

↓ – Decreases highlighted value.

`Fast ↑` – Increases highlighted value at greater increments.

`Fast ↓` – Decreases highlighted value at greater increments.



```
A:     Stopped
A:Primary Rate    25  ml/h
A:Pri VolRem(VR) 250  ml
A:Pri Time(TR)    10h 00m
A:Pri VolInf(VI)  10  ml
    since 12:37p 01 Feb 95
Press Select to choose line
Select   ↑    ↓    Fast ↑
```

Figure 7-7. Channel Programming Page

7.6.1 Programming Primary Infusion

Setting the Primary Rate

1. Press *A, B,* or *C* button to display the Programming Page for the desired channel.
2. Press **Select** if current rate is desired or Press ↑,↓, **Fast↑**, or **Fast↓** to change the Rate. Value flashes.
3. Press **Enter** to confirm and the highlight on the screen will move to the volume remaining (VR). Value flashes.

Setting Primary Volume Remaining (VR)

1. Press **Select** if current VR is desired or press ↑,↓, **Fast↑** or **Fast↓** to change VR.
2. Press **Enter** to confirm and the Primary time remaining (TR) will be calculated automatically based on the Vr and Rate. The Highlight will move to Volume Infused (VI)

Clearing Primary Volume Infused (VI)

1. Press **Select** if current VI is desired or press **Clear** to reset VI to zero. The date and time will be cleared.

The **Clear** button switches to *Recall*. Pressing the **Recall** button recalls the previous VI value.

2. Press **Enter** to confirm.
3. Open regulating clamp on administration set.
4. Press the **Start Stop** button to begin infusion.
5. Observe the following:

   The channel will start infusing

   The current time and date are entered.

   The green infusion light on the channel key stays lit.

   The display reverts the Standard Display Page after one minute.
6. Verify solution flow.
7. Press the *STANDARD DISPLAY* button.
8. Verify settings.

Setting Infusion by Rate/Volume or Volume/Time

1. Press the *STANDARD DISPLAY* button if the Standard Display page is not already displayed.
2. Press the *MORE OPTIONS* button and the **TotVol, Device, Config,** and **Note** buttons will appear.
3. Press **Config** and the first of five instrument Settings pages will be displayed.
4. Press **Select** to move the highlight to Setup Line Option.
5. Press↑ or ↓ to choose Yes to enable the Programming Option.
6. Press **Enter** to enable programming.
7. Press Channel buttons *A, B,* or *C.*
8. Press the *START STOP* button if the channel is infusing.
9. Press **Select** to move highlight to **Setup**. **Select VR and Time** or **Setup: Select VR and Rate**. If highlighted choice is not desired, use arrow buttons to change setup choice.
10. Press **Enter** when the choice flashes to accept. The highlight moves to the top of the page.

> NOTE
>
> The Rate will highlight but cannot be changed if the Volume/Time option is active. The Time Remaining selection will highlight but cannot be changed if Rate/Volume is active.

7.6.2 Making Changes During Primary Infusion

To titrate or change primary rate during infusion

1. Press *A, B,* or *C* buttons to display the programming page and highlight the rate.
2. Press **↑**, **↓**, **FAST↑**, and **FAST↓** buttons to change Rate. This will cause the Value to flash.
3. Press the **Enter** button to confirm. The new rate will begin infusing immediately.

To change volume remaining during infusion

1. Press *A, B,* or *C* buttons to display the programming page and highlight the rate.
2. Press **Select** to highlight VR.
3. Press **↑**, **↓**, **FAST↑**, and **FAST↓** to the change VR. This will cause the Value to flash.
4. Press **Enter** to confirm. The infusion will continue with new volume remaining.

To clear volume infused during infusion

1. Press *A, B,* or *C* buttons to display the programming page and highlight the rate.
2. Press **Select** to highlight VI.
3. Press **Clear** then **Enter** to reset volume infused to zero.
4. Press **Recall** button to recall the previous VI value or Press **Enter** to confirm. The infusion will continue with volume infused reset to zero and the current date and time are entered.

When the channel VI is cleared, that volume is not subtracted from the volume on the TotVol page. The date and time are cleared. The **Clear** button switches to **Recall.**

To simultaneously clear Total Volume Infused for all Channels

1. Press the *STANDARD DISPLAY* button to display the Standard Display page.
2. Press the *MORE OPTIONS* button and the **TotVol, Device, Config** and **Note** buttons will appear.
3. Press **TotVol** and the Total Volume page will be displayed and the VI for each channel and total pump VI values will be highlighted.
4. Press **ClrTot** to reset volume infused to zero. This will clear the date and time.
5. Press **Enter** to accept clearing of all values or press **Recall** to return to the previous Total VI.

To place a channel on Standby during infusion

1. Press the appropriate channel buttons *A, B,* or *C.*
2. Press the *START STOP* button to stop infusion.
3. Press the *STANDARD DISPLAY* button to display the Standard Display page.
4. Press *STNDBY.*

To start an infusion from Standby status.

1. Press the appropriate channel buttons *A, B,* or *C.*
2. Press the *START STOP* button to start infusion.

To resume infusion when Vr=0 (KVO) and a channel is infusing at the KVO rate

1. Press the appropriate channel *A, B,* or *C* button twice. The VR will be highlighted.
2. Press **Repeat** to recall the previous VR.
3. Press**↑**, **↓**, **FAST↑**, and **FAST↓** to change VR. The value will flash at this point.
4. Press **Enter** to confirm.
5. Press the START STOP button to resume infusion and the KVO rate.

> **NOTE**
> If the current infusion rate is set below KVO rate, the channel will infuse at the lower rate.

7.7 Secondary Infusion

This option allows two different rates of infusion to be administered sequentially. When secondary volume remaining reaches zero, primary infusion resumes automatically. To avoid the possibility of sympathetic flow during secondary delivery of intermittent medication, set up the administration set as recommended in Figure 7-8.

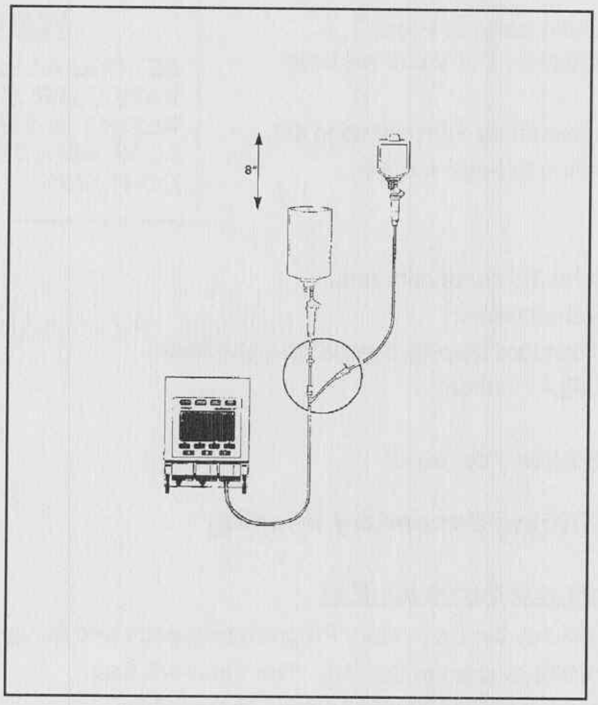


Figure 7-8. Secondary Infusion

7.7.1 Administration Set and Container Preparation

1. Use a 16-gauge needle to attach secondary set to primary upper "Y" site, below a check valve.
2. Prepare the secondary IV container according to Standard Operating Procedures.
3. Suspend the secondary solution container at least 8" above the primary solution container.
4. Press *A*, *B*, or *C* button to select a channel.

7.7.2 Programming Secondary Infusion

1. Press *A*, *B*, or *C* button to display the Primary Programming Page.
2. Press the *MORE OPTIONS* button.
3. Press the **2° Sec** button and the Secondary Programming Page is displayed.

Setting Secondary Volume Remaining

1. Press the Select button to highlight secondary VR, if necessary.
2. Press the **Repeat** button to enter the last VR selected or Press **↑**, **↓**, **FAST↑** and **FAST↓** to change VR. The VR will flash.
3. Press the **Enter** button to confirm.

> NOTE
>
> Secondary time remaining (TR) is calculated automatically, based on VR and Rate.
>
> The highlight will move to the secondary volume infused (VI).

Clearing Secondary Volume Infused (VI)

1. Press **Select** if current VI is desired or Press **Clear** to reset volume infused to zero. This will clear date and time and the **Clear** button switches to **Recall**.
2. Press **Enter** to confirm.

Setting Secondary Rate

1. Press **Select** if current rate is desired or Press **↑**, **↓**, **FAST↑**, or **FAST↓** to change rate. The Value will flash.
2. Press **Enter** to confirm.
3. Open regulating clamp on secondary administration set.
4. Press the *START STOP* button to begin infusion.
5. Observe the following:

   Four tones will sound.

   The Pump will start infusing at the secondary rate.

   The Current date and time are entered.

   The display reverts to the Standard Display page after one minute.
6. Press the *STANDARD DISPLAY* button.
7. Verify settings.
8. Verify solution flow from secondary container.

WARNING

SETTING A SECONDARY RATE OVER 275ML/H MAY RESULT IN SYMPATHETIC FLOW WITH THE PRIMARY CONTAINER.

7.7.3 Making Changes During Secondary Infusing

To titrate or change secondary rate during infusion

1. Press *A, B,* or *C* button to display the Secondary Programming page and to highlight the Rate.
2. Press **↑**, **↓**, **FAST↑**, and **FAST↓** to change the rate. The Value will flash.
3. Press **Enter** to confirm and the new rate begins infusing immediately.

To review or change Primary Value(s) during secondary infusion

1. Press *A, B,* or *C* button to display the Secondary Programming page.
2. Press the *MORE OPTIONS* button and **1° Pri** and **CalcOn** buttons will appear.
3. Press the **1° Pri** button and the Primary Programming Page will be displayed.
4. Press **Select** to highlight value(s) to change.
5. Press **↑**, **↓**, **FAST↑**, and **FAST↓** to change the value(s).

Channel Display on the standard display is reversed highlighted

6. Press **Enter** to confirm.

To Start Primary Infusion Before Secondary Completes

1. Close the regulating clamp on the secondary infusion set.
2. Press the *A, B,* or *C* button to display the Secondary Programming page._
3. Press the *MORE OPTIONS* button and **1° Pri** and **CalcOn** buttons will appear.
4. Press the **1° Pri** button and the Primary Programming Page will be displayed.
5. Press the *START STOP* button to begin primary infusion and stop secondary infusion.
6. Observe the following:

Four tones will sound.

The Pump will start infusing at the primary rate._

WARNING

PRESSING THE START/STOP BUTTON WOULD RESULT IN THE REMAINING SECONDARY MEDICATION BEING DELIVERED AT THE PRIMARY RATE.

7.8 Dose Rate Calculator

7.8.1 Dose Rate Calculator Programming For A Specific Drug Name

With this feature, the instrument calculates a volumetric or dose rate based on values entered for patient weight, drug concentration (drug amount and dilutent volume) and dosing parameters. If a dose is entered, the volumetric rate is calculated. If a volumetric rate is entered, the dose is calculated.

> NOTE
>
> Dose Rate programming page will not display if channel is infusing. If infusing is in secondary mode, switch to primary mode and stop infusion before proceeding.
>
> Pressing *A, B, or C* at any time during DRC set-up returns the highlight to the top of the page.

1. Press *A, B,* or *C* button to display the Primary Programming page.
2. If infusing already, press the *START STOP* button to stop infusion.
3. Press the *MORE OPTIONS* button and the **2°Sec** and **CalcOn** buttons will appear.
4. Press the **CalcOn** button and the Dose Rate Calculator programming page is displayed and **Drug?** Button is highlighted.

Programming a Drug

1. Scroll using arrow buttons to display alphabetized, abbreviated, and generic drug names.
   ↓ moves A to Z.
   ↑ moves Z to A.
   E.g. **Dopamine__mg/__ml** *and* **mcg/kg/min**
   Lidocaine__Gm/ml *and* **mg/min**
2. Press **Enter** when desired drug name is highlighted. The highlight will move to the **Wt** symbol on the screen.

> **WARNING**
>
> ENSURE CORRECT ENTRY OF ALL DRUG CALCULATION INFUSION PARAMETERS. CONSULT THE DRUG MANUFACTURERS LABELING FOR INFORMATION CONCERNING APPROPRIATE ADMINISTRATION GUIDELINES AND DOSAGES.

Changing the drug name clears the previous values and changes the drug concentration and dose rate parameters appropriate for the selected drug.

Programming Weight

1. Choose the patient's kilogram weight using the arrow buttons.
2. Press **Enter** when desired weight is displayed.

The highlight will move to **Conc**.

Programming a Concentration

1. Choose **Conc** using the arrow buttons.
2. Press **Enter** when desired concentration is displayed. The Highlight will move to Value for dilutent volume.
3. Choose the dilutent volume using the arrow buttons.
4. Press **Enter** when the desired volume is displayed.

VR is automatically set when the dilutent volume value is internal but can be changed if desired. The highlight moves to the **Dose** button.

Programming a Dose

1. Choose dose using the arrow buttons.
2. Press **Enter** when the desired dose is displayed.

The Volumetric rate is automatically calculated. The highlight moves to **Rate**.

Changing Volumetric Rate

1. Choose the rate value using the arrow buttons if the dose rate is not desired.
2. Press **Enter** when the desired volumetric rate is displayed.

When the rate is changed, the dose value is automatically calculated. The highlight moves to VR.

Changing the Volume Remaining

1. Change the VR value using the arrow buttons.
2. Press **Enter** when the desired VR is displayed.

The highlight will move to VI.

Clearing the Volume Infused (VI) and Dose Infused (DI)

1. Press **Clear** then **Enter** to reset volume infused to zero. The highlight moves to DI.
2. Press **Clear** then **Enter** to reset dose infused to zero.
3. Open the regulating clamp.
4. Press the *START STOP* button to begin infusing.

The channel starts infusion. The display switches to the Standard Display page after 1 minute. The DRC parameters are displayed.

5. Verify fluid flow.
6. Press the *STANDARD DISPLAY* button.
7. Verify settings.

Changing DRC Values while Infusing

> NOTE
> Stop infusion to make changes to the drug name, weight or concentration.

1. Press *A, B,* or *C* button.

The Dose Rate Calculator programming page is displayed. The dose value is highlighted.

2. Press **Select** to scroll through values that can be changed.
3. When the highlight is on the value to be changed (Dose, Rate, VR, VI, DI), use the arrow buttons until the desired value is displayed.

   When the dose is changed, rate is automatically recalculated.

   When rate is changed, dose is automatically recalculated.

   When the highlight is on value for VI or DI, the **Clear** button becomes active. Pressing the **Clear** button changes the value to 0.0.
4. Press **Enter** after each value change to accept the new value to begin infusing at the new rate immediately.
5. Press the *STANDARD DISPLAY* button.
6. Verify settings.

> NOTE
> Calculated rates for infusion are fractional and will be displayed as a fraction on the Standard Display even if Device Type is set for whole numbers.

7.8.2 Dose Rate Calculator Programming with "Drug?"

The Drug? Selection can be used to calculate a drug not listed in the pump or for an alternate dosing regimen.

> **NOTE**
>
> Dose Rate programming page will not display if channel is infusing. If infusing is in secondary mode, switch to primary mode and stop infusion before proceeding.
>
> If instrument is off for more than five minutes, the DRC mode will revert to the primary mode.

1. Press *A, B,* or *C* button to display the primary programming page.
2. Press the *START STOP* button if the channel is infusing.
3. Press the *MORE OPTIONS* button and the **2°Sec** and **CalcOn** buttons will appear.
4. Press **CalcOn** and the Dose Rate Calculator programming page is displayed and the **Drug?** Button is highlighted.
5. Press **Select** and the highlight moves to Wt.

Programming Weight

1. Choose the patient's KG weight using the arrow buttons.
2. Press **Enter** when the desired weight is displayed.
3. The highlight will move to the **Conc** button.

Programming Concentration

1. Choose the concentration using the arrow keys.
2. Press **Enter** when desired concentration is displayed. The highlight will move to the concentration parameters.
3. Choose the desired concentration parameters using the arrow buttons.
4. Press **Enter** when the desired parameters are displayed. The highlight will move to the value for the dilutent volume.
5. Press **Enter** when the desired volume is displayed.

VR is automatically set when the dilutent volume is entered, but can be changed if desired. The highlight moves to **Dose** parameters.

Programming Dose

1. Choose the dose parameters (measure/ weight/ time) using the arrow buttons.
2. Press **Enter** when each desired dose parameter is displayed.

The highlight will move to the next parameter each time **Enter** is pressed. The highlight moves to **Dose** when **Enter** is pressed to accept the time value.

3. Choose the dose using the arrow buttons.
4. Press **Enter** and the highlight will move to the **Rate** parameters.

Changing Volumetric Rate

1. Choose the volumetric rate using the arrow buttons if the dose calculation is not desired.
2. Press Enter when the desired rate is displayed.

When the rate is changed, the dose is automatically calculated. The highlight moves to VR.

Changing Volume Remaining

1. Choose the VR value using the arrow buttons.
2. Press **Enter** when the desired VR is displayed.

The highlight will move to the VI.

Clearing Volume Infused (VI) or Dose Infused (DI)

1. Press **Clear** then **Enter** to change VI value to 0.

The highlight will move to DI.

2. Press **Clear** then **Enter** to change DI value to 0.
3. Open the regulating clamp.
4. Press the *START STOP* button to begin infusion.

The channel will start infusing. The Display switches to the Standard Display page after 1 minute. DRC parameters are displayed.

5. Verify fluid flow.
6. Press the *STANDARD DISPLAY* button.
7. Verify settings.

7.8.3 Discontinuing DRC Option

1. Press *A, B,* or *C* button to display the Dose Rate Calculator programming page.
2. Press the *START STOP* button to stop if infusing.
3. Press the *MORE OPTIONS* button.
4. Press **CalcOff**.

The display reverts to the primary programming page. Volumetric rate, volume remaining and volume infused from DRC is carried over to the primary programming page.

7.9 Instrument Setting Options

7.9.1 Settings Information

1. Press the *STANDARD DISPLAY* button.
2. Press the *MORE OPTIONS* button and **TotVol, Device, Config** and **Note** buttons will appear.
3. Press **Select** to move the highlight through the list.
4. Press ↑, ↓, to change a highlighted setting.
5. Press the *STANDARD DISPLAY* button to exit the Instrument Settings page.

The **Select** button changes to **Enter** and **Next Pg** button changes to **Recall** when a setting is changed.

7.9.2 Changing Device Type

There are six device types with preset parameters (Table 7-1) that accommodate specific clinical applications.

General Purpose
Neonatal
Controller Pressure
Operating Room
General Purpose II
Operating Room II.

When setting up the pump, select the device type that best suits the clinical needs at hand. The abbreviated name of the Device Type appears as a button on the Standard Display page. Pressing the button displays the device type on the prompt line.

1. Press the *STANDARD DISPLAY* button.
2. Press the *MORE OPTIONS* button and the **TotVol, Device, Config**, and **Note** buttons will appear.
3. Press the **Device** button. The currently selected Device Type has an asterisk and is highlighted.
4. Press **Select** to move the highlight through the list.
5. Press **Enter** when the desired device is highlighted.

If preset values are compatible with the newly selected device type and asterisk will appear next to the device name.

If the Channel is **not** infusing when the device type is changed and preset values are **not** compatible with the newly selected device type:

The display switches to a notification screen.

Incompatible Channel(s) indicated.

1. Press **Yes** or **No** when prompted.
2. If **No**, the display reverts to Change Device Type page to select another device type.

   If Yes, observe the following:

   Incompatible values are cleared.

   Display reverts to Standard Display page.

   New Device Type becomes active.

If the Channel **is** infusing when the device type is changed and preset values are **not** compatible with the newly selected device type:

The display switches to the notification screen.

Incompatible Channel(s) is indicated.

1. Press **Yes** or **No** when prompted.
2. If **No**, Display reverts to Change Device Type page to select another device type.

   If **Yes**, observe the following:

   The pump will alarm.

   Infusion will stop on affected channel.

   Display reverts to Standard Display with Alarm indicated in affected channel.
3. Press affected channel *A, B,* or *C* and follow the instructions displayed.

Table 7-1. Preset Parameters[†]

Default Parameter	General Purpose	Neonatal	Controller Pressure	Operating Room	General Purpose II	Operating Room II
Occlusion Detection Method	Baseline	Baseline	Absolute Threshold	Baseline	Baseline	Baseline
Occlusion Alarm Setting	Baseline 5 psi	Baseline +3 psi	Absolute 3ft H_2O	Baseline +5 psi	Baseline +5 psi	Baseline +5 psi
Maximum Pressure	15 psi	15 psi	3 ft H_2O	15 psi	15 psi	15 psi
Air-in-line Alarm Threshold	500 μl	50 μl	500 μl	500 μl	500 μl	500 μl
KVO Rate*	3 ml/h	1.0 ml/h	3 ml/h	3 ml/h	3.0 ml/h	3.0 ml/h
Rate Range	1-999 ml/h	0.1-99.9 ml/h	1-299 ml/h	1-999 ml/h	0.1-999 ml/h	0.1-999 ml/h
Maximum VR Setting	9999 ml	9999 ml	9999 ml	9999 ml	9999 ml	9999 ml
Pump Not In Use Advisory	Yes	Yes	Yes	No	Yes	No
ALL Setting for VR	N/A	N/A	N/A	Option	N/A	Option

* Channel will infuse at the KVO rate shown in table or at the current infusion rate, whichever is lower.

[†] The Values shown in the above table can be modified to meet the organizations requirements using optional FMS software at the next higher level of maintenance. To review actual default parameters on a MedSystem III pump, select a Device Type and refer to Instrument Settings pages (Screens) 2 through 5. An asterisk appears beside settings which are not factory default.

7.9.3 Changing Configuration Settings

Maximum rate, maximum volume, pressure and air-in-line threshold are configured at the factory. These parameters can be modified to meet specific requirements using the optional (Field Maintenance Software) FMS software. The Config option allows the operator to view and/or change some instrument settings. Items that can be changed are shown in Table 7-2.

Additional configuration screens can only be changed by qualified personnel using the optional FMS software.

Table 7-2. Configuration Settings

Option	Choices	Description
Audio Volume:	low medium high highest	A tone accompanies each level to aid in determining volume choice. If an alarm is ignored, the volume will ramp to the highest audio unless disabled by FMS.
Sec Complete Advisory:	Yes No	Pump sounds two tomes and displays advisory when secondary VR = 0.
Setup Line Option:	No Yes	Enables infusion to be set up as rate/volume or volume/time. Stop infusion before modifying this line option.
Time:	24 hr am/pm	Allows pump to be set with a 12 or 24 hour clock.
Hour/minutes	0000-2359	} Each item can be adjusted when highlighted.
Day	1-31	
Month	Jan-Dec	
Years	00-99	

7.9.4 Viewing Note

The Note button accesses the Special Note Message page. When Note is programmed, it appears when the pump is turned on.

> NOTE
>
> If no information has been programmed on the note page, there will be a two-tone advisory and the message: **THERE IS NO SPECIAL NOTE** will display on the prompt line.

1. Press the *STANDARD DISPLAY* button.
2. Press the *MORE OPTIONS* button and the **TotVol, Device, Config** and **Note** buttons appear.
3. Press the **Note** button and note information is displayed.
4. Press **Enter** to accept or press **Recall** to recall the previous setting.

7.10 Batlog History

To Display **Batlog** History:

1. Press *STANDARD DISPLAY*.
2. Press *MORE OPTIONS*.
3. Press *MORE OPTIONS* again.

Batlog and **DemoWD** softkeys appear.

4. Press **BatLog** softkey.

The Battery History page is displayed. Display switches to Standard Display after 1 minute **OR** Press Standard Display to exit Battery History page.

7.11 Infusion Pump Diagnostics

The Drug Infusion Pump provides internal diagnostics and displays Advisories and Alarms on its display. Table 7-3 defines the messages, conditions and corrective action(s) required.

7.11.1 Alarm Overview

To respond to an advisory, alarm, or fault message:

1. Press QUIET
   Audio tone stops
   Red light flashes on affected channel
2. Press affected channel A, B, or C and alarm information will be displayed.
3. Take appropriate action(s) indicated on the display.
4. Press ***START STOP*** to resume infusion.

Alarm Response Keys and definitions:

QUIET	Silences Advisories, Alarms, and faults for two minutes. Soft key is accessible during alarm status.
CANCEL	Clears alarm and advisory messages and stops tone. Use when alarm or advisory condition cannot be corrected or Operator chooses not to correct
ClrAir	Moves air bubbles past air-in-line sensor. Each press of the ClrAir soft key displaces 0.2 ml of air and fluid. Three beeps indicate when air bubble is no longer in front of the air-inline sensor.
CONFIRM	Is present during Check Fluid Side alarms. Allows infusion to continue if no up stream occlusion is found and fluid is flowing in drip chamber.
RETRY	Resets resemble fault conditions. Used when attempting to re-establish normal operation of a channel.
SERVICE	Disables use of affected channel. Servicing of the pump is required before channel can be used

Table 7-3. Infusion Pump Failures Advisories and Alarms

Message	Condition	Corrective Action
None	MIP fails to Power-On	Check if LSTAT on and circuit breakers not tripped. If on, re-attempt MIP Power-on. If no success remove contact IMS support.
None	Screen too light or too dark to read with pump on	Press *STANDARD DISPLAY* and press *Cntrst* soft key to change screen contrast.
None	Soft keys do not function	Recycle power to MIP. If no success contact IMS support.
None	Pump shut off; Low Power Pump shut down.	Reconnect power if it has been shut off..
None	Blank screen-instrument error condition.	Turn off pump, then on again. Press *START/STOP* to resume each channel that had been infusing. If condition persists, contact IMS support.
Two beeps, slow flashing red-light on infusing channel's channel key; infusion continues:		Advisory
Check Air Sensor	Air detected in tubing, tubing collar not properly seated or air sensor is dirty or damaged.	Verify tubing collar is fully seated in air sensor recess. Verify tubing in air sensor recess is not damaged, twisted or dirty. Press *ClrAir* on channel's Alarm information page. Three beeps indicate air bubble is no longer in front of air sensor. If air is still present, remove cassette and manually clear air according to Standard Operating Procedures (SOP). If no air is present, clean air sensor recess as directed in cleaning instructions.
Infusion Complete VR=0	VR has counted down to zero. Channel is infusing at KVO rate.	Enter new VR or, if same volume is desired, press *REPEAT*. Press *Enter*. Press START/STOP to resume primary infusion rate.

Message	Condition	Corrective Action
Low Battery	30 minutes or less battery power remaining	Connect the MIP to external power via the LSTAT.
Battery Depleted	Insufficient battery power. The pump will shut down in 5 minutes.	Connect the MIP to external power via the LSTAT. Press START/STOP to resume infusion(s).
Channel Not In Use	Two minutes have elapsed since cassette was installed or infusion was stopped.	Remove Cassette OR Press *START/STOP* to start infusion OR Press *STNDBY* to place channel on Standby.
Four rapid beeps, infusion stops, rapidly flashing red light on channel key:		
Air In Line	Air detected in fluid pathway during infusion, or air sensor is dirty.	Verify tubing collar is fully seated in air sensor recess. Verify tubing in air sensor recess is not damaged, twisted or dirty. Press *ClrAir* soft key on channel's Alarm information page. Three beeps will indicate air bubble is no longer in front of air sensor. (NOTE: Each press of he the *ClrAir* soft key displaces 0.2ml or air and fluid and updates channel's VR and VI calculations.) If air is still present, remove cassette and manually clear air according to standard organizational procedures. If no significant air is present, clean air sensor recess as directed in cleaning instructions. Set up pump at, or slightly below, IV site to minimize formation of micro bubbles. Press *START/STOP* to resume infusion.
Air In Lower Tubing	Air bubbles detected in fluid pathway with a total volume exceeding the air in line threshold setting.	Check administration set for leaks. Check lower tubing for multiple small air bubbles. Press ClrAir soft key on channel's Alarm information page. Three beeps will indicate air bubble is no longer in front of air sensor. (NOTE: Each press of he the *ClrAir* soft key displaces 0.2ml or air and fluid and updates channel's VR and VI calculations.) If air is present clear in accordance with organizational SOP's. Set up pump at or slightly below, IV site to minimize formation of micro bubbles. If no significant air is present, press *START/STOP* to resume infusion.
Cassette Jammed	Cassette piston is difficult to move or piston sleeve is loose.	Remove cassette, check placement of soft, plastic piston sleeve and reposition, if necessary. If condition persists, try cassette in a different channel. Replace administration set if alarm recurs or if piston does not move freely. If Alarm recurs with several cassettes, channel may need service.

Message	Condition	Corrective Action
Cassette Not Latched	Cassette is partially disengaged or latching mechanism is dirty.	Push cassette latch completely in. Ensure slide clamp is flush with entire cassette. Press *START/STOP* to resume infusion. If condition persists, try cassette in a different channel. Replace administration set if alarm recurs. Clean lower assembly according to Cleaning instruction.
Cassette Removed	Cassette is removed from holder while channel is infusing.	Reinstall cassette, and press *START/STOP* to resume infusion. OR Press *CANCEL*.
Check Fluid Side	Possible upstream restrictions to flow.	Check tubing between container and pump for a closed regulating clamp, closed vent (with unvented container), kinked tubing, empty syringe, or a restriction to flow. If no occlusion present, press *CONFIRM*. Press *START/STOP* to resume infusion. Verify fluid is flowing in drip chamber. A ✓ appears on standard display to indicate Confirm has been pressed.
Faulty Cassette	Cassette may be damaged or inoperable. Possible dysfunction of cassette sensor located in holder.	Reinsert cassette into another channel. If alarm persists, replace administration set. If alarm recurs with two cassettes in the same channel, contact IMS support.
Fluid Side Occluded	Upstream restriction to flow.	Check tubing between container and pump for a closed regulating clamp, closed vent (with unvented container), kinked tubing, empty syringe, or a restriction to flow. Clear occlusion. Press *START/STOP* to resume infusion.
Pumping Latch Closed	Pumping latch jaw located to right of air sensor is closed or broken.	Using only your finger, push down pumping latch jaw until it snaps open. If pumping latch jaw is visibly broken contact IMS support. CAUTION: NEVER USE A BLUNT INSTRUMENT TO OPEN A CLOSED PUMPING LATCH.
Rate/Vol Settings Cleared	Rates and/or volumes are incompatible with newly selected Device Type.	Re-enter settings as required. Press *START/STOP* to resume infusion.

CHAPTER 8 VENTILATION

8.1 Intended Use and Limitations

The ventilator apparatus is an electronically controlled ventilator, compressor, and air/oxygen mixer. It is designed to deliver Assist-Controlled Ventilation (ACV), Synchronized Intermittent Mandatory Ventilation (SIMV), and Continuous Positive Airway Pressure (CPAP) with or without Positive End Expiratory Pressure (PEEP) or SIGH. PEEP is compensated for altitude to minimize the patient's work-of-breathing. The ventilator also includes a gas flow sensor for additional data gathering.

Do not operate Ventilator at temperatures below -25°C or above 65°C.

8.2 Accessories

Use the accessories listed in Appendix D where called out in this section.

The Ventilator may be operated with a humidifier or heat moisture exchanger (HME). Humidifiers should be connected and operate in accordance with directions provided by its manufacturer. Humidifiers are not recommended for use in transport. Observe all safety the cautionary statements.

HME's, sometimes referred to as "artificial noses", are not position-sensitive, and are recommended for transport applications. While HME's may not be suitable for all applications, they facilitate portability in a way that conventional humidifiers cannot. Choose an HME carefully. Look for one that is lightweight and has minimal dead-space and minimal resistance to flow. HME's attach between the disposable ventilator circuit and patient's endotracheal tube (Figure 8-5).

8.3 Controls, Displays and Connectors

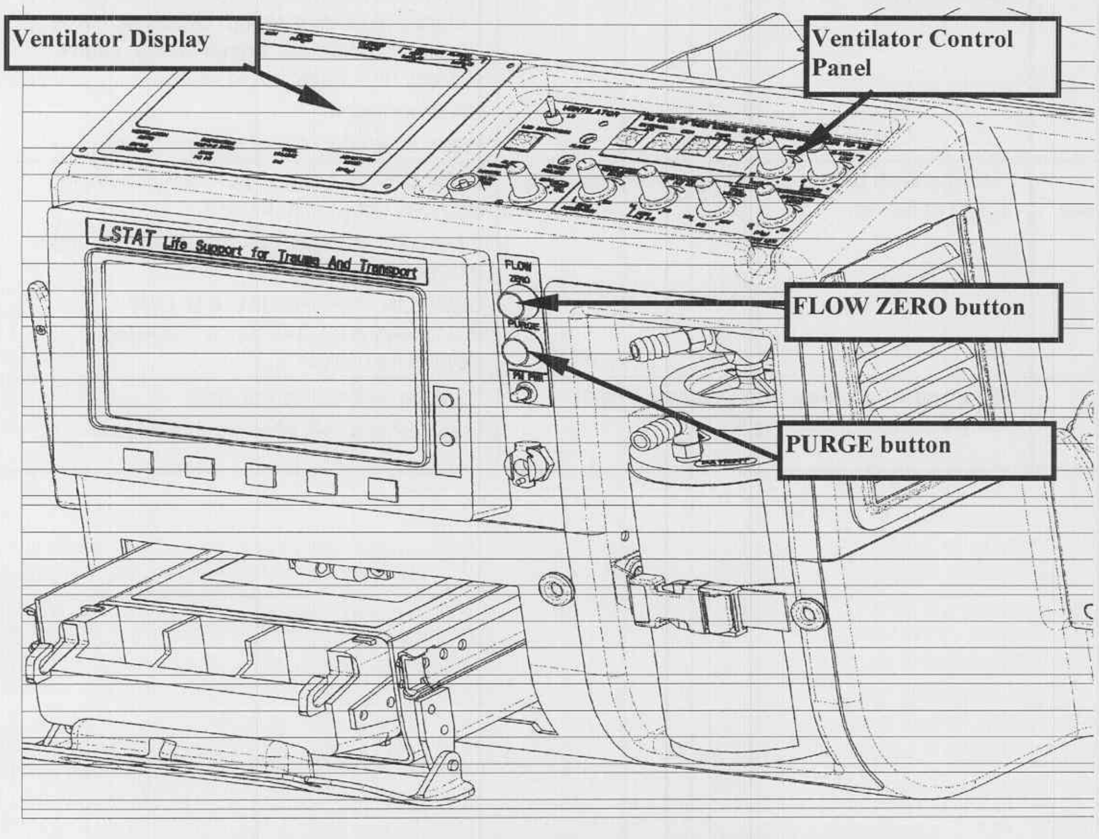


Figure 8-1. Ventilator and Flow Sensor Controls and Displays

8.3.1 Controls

The flow sensor controls (*FLOW ZERO AND PURGE*) are located on the outboard side of the head fairing (Figure 8-1). Where applicable, corresponding information is displayed on the ventilator display.

Flow Sensor

The flow sensor is operable through the *SYSTEM POWER*. It does not consume gas for operating power. All gas is dedicated to patient care.

NOTE

To minimize the effects of aerosolized medications on the flow sensor, it is recommended that the flow sensor be removed from the ventilator circuit prior to the delivery of the medication. **The decision to remove or not remove the flow sensor is the responsibility of the clinician.**

Water will condense in the pressure sensor lines at a faster rate when used in cooler ambient temperatures.

Always keep the flow sensor tubing pointed in an upward position to minimize pooling of water and secretions at the pressure sense line openings.

Flow Purge

The Ventilator has a manual and automatic flow purge capability. Manual purging is described in Table 8-1. The automatic function automatically purges the pressure sense lines every 2 minutes, 5 minutes, or 10 minutes depending on system conditions.

A double lumen connecting line connects the flow sensor to the ventilator. The system will purge one side of the line and then the other during each purge cycle. The frequency of the purge is primarily dependent on ventilator circuit pressure. At low circuit pressure (0-20cmH2O) the system will purge every 10 minutes. As circuit pressure increases (21-40 cmH2O) the system purges every 5 minutes. When the circuit pressure is greater than 40 cmH2O, the system purges every 2 minutes. This action anticipates increased moisture migration into the pressure sense lines due to the increase in circuit pressure.

NOTE

During the purge cycle the pump will be heard.

The automatic purge mode may not be disabled.

During a very low battery condition, automatic and manual purging is not allowed.

Flow Zero

The flow sensor has a manual and automatic Flow Zero function. The manual function is described in Table 8-1. The frequency of the automatic flow zero depends on monitoring conditions. In either the automatic or manual mode, the flow sensor zero takes no longer than 2 to 3 seconds. When the ventilator is operated from a cold start, the internal temperature of the system will gradually warm to its nominal operating temperature. During this period, a flow sensor zero will occur approximately once per minute. As the temperature reaches nominal, the frequency of the flow sensor zero increases to every 10 minutes. If the ventilator is placed into operation from the standby mode, the flow sensor zero will occur every 10 minutes since the ventilator is already at it nominal temperature. Also, a flow sensor zero will occur after every automatic or manual purge.

The ventilator controls are located on the top of the head fairing (Figure 8-1 and Figure 8-2). All ventilator control settings, except *MODE SELECTOR*, appear on the ventilator display's upper and lower lines (Figure 8-3). Table 8-1 describes the ventilator control functions.

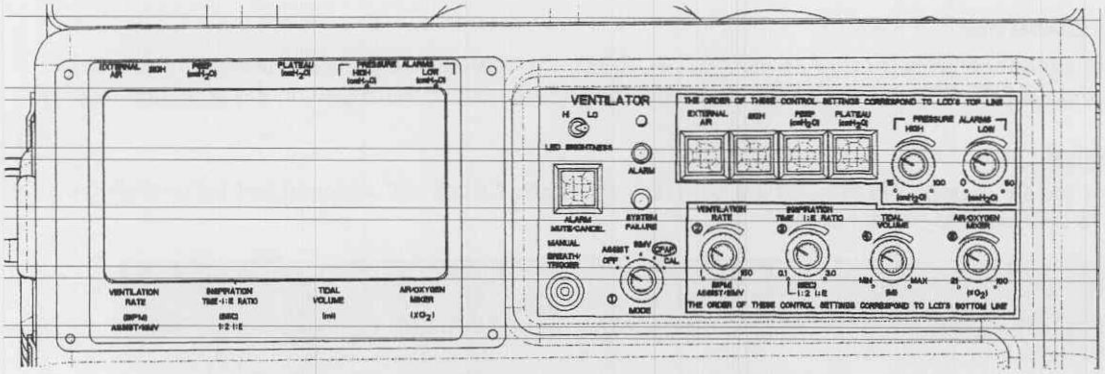

EXTERNAL AIR
SIGH
PEEP (cmH2O)
PLATEAU (cmH2O)
PRESSURE ALARMS
HIGH (cmH2O)
LOW (cmH2O)
VENTILATION RATE (BPM) ASSIST/SIMV
INSPIRATION TIME - I:E RATIO (SEC) 1:2 I:E
TIDAL VOLUME (ml)
AIR/OXYGEN MIXER (%O2)
VENTILATOR
HI
LO
LED BRIGHTNESS
ALARM
ALARM MUTE/CANCEL
SYSTEM FAILURE
MANUAL BREATH/ TRIGGER
ASSIST OFF
SIMV
CPAP
CAL
MODE
THE ORDER OF THESE CONTROL SETTINGS CORRESPOND TO LCD'S TOP LINE
15
100
0
50
THE ORDER OF THESE CONTROL SETTINGS CORRESPOND TO LCD'S BOTTOM LINE
MIN
MAX
21
0.1
3.0

Figure 8-2. Ventilator Controls and Display (Top View)

Table 8-1. Flow Sensor and Ventilator Control Descriptions

Control	Description
FLOW ZERO (Figure 8-1)	The manual FLOW ZERO button may be used if a positive or negative offset of the flow waveform from zero baseline is observed. The condition mainly occurs if the orientation of the flow sensor has changed since the last flow sensor zero. Press the button to correct the offset. If the offset does not clear after another flow sensor zero, then replace the flow sensor with a new one and observe the flow waveform.
PURGE (Figure 8-1)	The manual PURGE button may be required to be used in between the automatic purge cycle. It may be used as often as needed and may be used at all times. Pressing the button will purge the gas flow sensor lines of accumulated fluids. It will purge one side of the line and then the other during each purge cycle.
LED BRIGHTNESS HI/LO	The toggle switch setting selects the LED brightness level. Choose HI for normal viewing, or LO for use in reduced lighting situations.
EXTERNAL AIR OFF/ON	Permits manual selection of external compressed air as a primary air source. When the Ventilator is turned ON, its CPU "samples" the respective gas fitting and looks for an air pressure greater than 40 PSI. If a lower pressure, or no pressure is sensed, the LCD will display "OFF" (default value), and the CPU allows operation from the internal compressor. If a pressure exceeding 40 PSI (+/- 2 PSI) is sensed, the LCD will display "ON" and allow operation from "ON to "OFF". Attempting to select "ON" with less than 35 PSI (+/- 2 PSI) present will cause an alarm to sound. The LCD display area for EXTERNAL AIR is on the top line, far left position. The EXTERNAL AIR OFF/ON display will blank when a SYSTEM FAILURE alarm occurs.
SIGH OFF/ON	Permits the ventilator to operate with or without SIGH. When activated, the first ventilator generated breath will be a SIGH. Additional SIGH ventilations are delivered once every 100 ventilations or 7 minutes, whichever occurs first. Each SIGH ventilation equals 150% for the INSPIRATION TIME setting (and exhalation period), which increases delivered volume by 50%. Proportionately increasing both the inspiration and exhalation time allows ventilator to maintain I:E during SIGH. As a safety precaution, the ventilator does not allow the inspiratory portion of a SIGH breath to exceed 3 seconds. Manually pressing this push button will toggle the display from "OFF" to "ON", or from "ON to "OFF". "OFF" is its default value. SIGH becomes disabled ("OFF") in the CPAP mode, or when the PRESSURE PLATEAU is selected ("ON"). The LCD display area for SIGH is on the top line, second position from the left. The SIGH OFF/ON display will blank when a SYSTEM FAILURE Alarm occurs.
PEEP OFF/ON-SET	Activates Ventilator 's internal control. When the ventilator is turned ON, PEEP has a default value of 0 cmH_2O (no PEEP). Pressing the push button allows a PEEP value to be manually entered (see section 8.8.5 USING POSITIVE END EXPIRATORY PRESSURE). The LCD display area for PEEP is on the top line, third position from the left. The PEEP OFF/ON-SET display will blank when a SYSTEM FAILURE Alarm occurs.

Control	Description
PRESSURE PLATEAU OFF/ON	Permits ACV or SIMV operation with a pressure plateau. When the ventilator is turned ON, PLATEAU is OFF (default value). Pressing this push button activates a PLATEAU value that is referenced 10 cmH_2O below the HIGH PRESSURE ALARM/PEAK INSPIRATORY PRESSURE RELIEF Control set point. Its absolute range is 5 to 90 cmH_2O. When this push button is pressed, it will toggle the display from "OFF" to its PLATEAU value, or from its PLATEAU value to "OFF". PRESSURE PLATEAU becomes disabled ("OFF") in the CPAP mode. The LCD display area for PRESSURE PLATEAU is on the top line, third position from the right (see section 8.8.6 USING PRESSURE PLATEAU). The PRESSURE PLATEAU OFF/ON display will blank when a SYSTEM FAILURE Alarm occurs.
HIGH PRESSURE ALARM/PEAK INSPIRATORY PRESSURE RELIEF	Used to select HIGH PRESSURE ALARM and PEAK INSPIRATORY PRESSURE RELIEF setpoint. It has an absolute range from 15 to 100 cmH_2O. When the ventilator is turned ON, the HIGH PRESSURE ALARM/PEAK INSPIRATORY PRESSURE RELIEF Control setpoint value equals its current position. The LCD displays area for HIGH PRESSURE ALARM/PEAK INSPIRATORY PRESSURE RELIEF Control setpoint is on the top line second position from the right. The HIGH PRESSURE ALARM Control setting display will blank when a SYSTEM FAILURE Alarm occurs.
LOW PRESSURE ALARM	This control is used to select the LOW PRESSURE ALARM setpoint. It has an absolute range from 0 to 50 cmH_2O. When the ventilator is turned ON, the LOW PRESSURE ALARM Control setpoint value equals its current position The LCD display area for the LOW PRESSURE ALARM Control setpoint is on the top line, far right position. The LOW PRESSURE ALARM Control setting will display blank when a SYSTEM FAILURE Alarm occurs.
ALARM MUTE/CANCEL	Depending on the alarm category, the ALARM MUTE/CANCEL button can either mute an audible alarm signal, or cancel a particular alarm function: **ALARM MUTE** Pressing the button mutes the audible component for an Operating Alarm condition for predetermined period (see section 8.4 Alarms & Indicators). Alarm muting is reset when the current alarm condition no longer applies or the predetermined mute-period is reached (audible alarm will resound). A new alarm condition overrides a "muted" pre-existing alarm. When an alarm causing condition occurs, the LCD ALARM MESSAGE CENTER will display the pertinent alarm message. The ALARM LED alternately flashes, at the same frequency as the accompanying audible alarm. Pressing the ALARM MUTE/CANCEL Push button switch causes the ALARM LED to stay on continuously. It will resume flashing when the mute period ends. If a new alarm condition occurs during the mute period of a previous alarm, the new alarm will nave no effect upon the display of that alarm. The new alarm will cause the ALARM LED to alternately flash and respond as previously described when the ALARM MUTE/CANCEL Push button switch is pressed. **CANCEL** When pressed, the ALARM MUTE/CANCEL button cancels the audible component of an Advisory Alarm condition (see section 8.4 Alarms & Indicators). During an APNEA alarm condition, it will cancel both the audible and visual APNEA alarms and the controlled ventilation that are automatically invoked at the onset of apnea. Cancellation of an APNEA alarm allows Ventilator to resume operation at the preset ACV, SIMV, OR CPAP settings.

Control	Description
MANUAL BREATH/TRIGGER	The MANUAL BREATH/TRIGGER pushbutton is operable two ways: Pressing this control during normal CPU operation delivers one MANUAL BREATH. Each MANUAL BREATH is equal to one complete ventilatory cycle consisting of the current INSPIRATORY TIME/TIDAL VOLUME settings and expiratory period. In the CPAP mode, a manual breath is delivered at a flow rate of 30 liters per minute (LPM), an inspiratory time of 1.67 seconds, and pressure limited at 40 cmH_2O. A MANUAL BREATH cannot be delivered until airway pressure has reached baseline (zero or PEEP). Each time a MANUAL BREATH is triggered, an audible beep is heard. This control functions as a MANUAL TRIGGER backup, if a CPU failure occurs in the primary system. The MANUAL TRIGGER contains dedicated circuitry capable of providing manually triggered breaths. For as long as this push button is depressed, the MANUAL TRIGGER delivers a continuous gas flow at 30 LPM. A pressure relieving mechanism, contained within this circuit, limits peak inspiratory pressure from exceeding 40 cmH_2O. The MANUAL BREATH/TRIGGER Push button is protected against accidental contact by a circular guard.
MODE	Provides Operating power in the ACV, SIMV, CPAP, and CAL positions. Turning the MODE SELECTOR switch from OFF to A/C, SIMV, or CPAP causes the microprocessor to perform a "SELF CHECK" (see section 8.6.2 SELF CHECK) before initiating operating in the selected mode. Ventilator operation will not begin until "SELF CHECK" is successfully completed. Calibration of the airway pressure transducer is permitted in CAL position only (see section 8.6.3 TRANSDUCER CALIBRATION).
VENTILATION RATE	Determines the mechanical ventilation rate for ACV and SIMV operation. It is not operable in CPAP (RATE = 0). Its range is from 1 to 150 breaths per minute (BPM). When the ventilator is turned ON, the VENTILATION RATE Control setpoint value equals its current position. The LCD display area for VENTILATION RATE Control setpoint is on the bottom line far left position. During APNEA, the RATE Control setting and its LCD display will change to 12 BPM. The VENTILATION RATE Control setting display will blank when a SYSTEM FAILURE Alarm occurs, or the CPAP mode is selected.
INSPIRATION TIME/I:E RATIO	The INSPIRATION TIME/I:E RATIO Control sets the inspiratory duration of all ventilator-delivered breaths. It is adjustable in 0.1 second increments from 0.1 to 3.0 seconds maximum. Its usable range is limited by the VENTILATION RATE Control setting. Inverse I:E Ratio's (inspiratory time is greater than expiratory time) are not permitted. (See section 8.4.2 Non-operating Alarms). A default I:E ratio of 1:2 is activated when this control is turned to its fully counterclockwise position. When the ventilator is turned ON, the INSPIRATION/TIME I:E RATIO Control setpoint value equals its current position. Setting INSPIRATION TIME causes the resulting I:E RATIO to be calculated. Setting the default I:E RATIO (1:2) causes the INSPIRATION TIME to be calculated when the VENTILATION RATE settings are changed. Inspiration time and I:E ratio are simultaneously displayed in the LCD. The LCD display area for INSPIRATION TIME/I:E RATIO Control setpoint is on the bottom line, second position from the left. The INSPIRATION TIME/I:E RATIO Control settings display will blank when a SYSTEM FAILURE Alarm occurs or CPAP is selected. It will blink during INVERSE I:E conditions.

Control	Description
TIDAL VOLUME	Allows gas to be delivered over a wide range. Its maximum flow is equivalent to approximately 1000ml/sec (60 LPM). TIDAL VOLUME may be obtained from any of the following gas or gas combinations: • External Air (Cylinder) • External Compressed Air (Cylinder) • Internal Air Compressor • External Oxygen and External Air Cylinder or Compressor, or Internal Air Compressor • External Oxygen Tidal Volume is calculated and displayed in milliliters (ml). When the ventilator is turned ON, the TIDAL VOLUME Control setpoint value equals its current position. The Ventilator CPU monitors and adjusts gas flow. Its LCD initially displays "####set" TIDAL VOLUME for the first one or two delivered breaths, the CPU makes whatever flow corrections are required, then the LCD alternately displays "####set" TIDAL VOLUME and "####del" TIDAL VOLUME. The LCD display area for TIDAL VOLUME Control setpoint is on the bottom line, second from the right. The TIDAL VOLUME Control setting display will blank when a SYSTEM FAILURE Alarm occurs or CPAP is selected.
AIR/OXYGEN MIXER	Allows air, oxygen, or mixtures of air and oxygen to be delivered. It has a range of 21% (all air) to 100% (all oxygen) and may be obtained from the following gas or gas combinations: • 21% FIO_2 from External Air (Cylinder) • 21% FIO_2 from External Compressed Air (Compressor) • 21% FIO_2 from Internal Air Compressor • 21 to 100% FIO_2 from External Oxygen and External Air Cylinder or Compressor • 21 to 100% FIO_2 from External Oxygen and Internal Air Compressor • 100% FIO_2 from External Oxygen When the ventilator is turned ON, the AIR/OXYGEN MIXER Control setpoint value equals its current position. The ventilator CPU adjusts gas flow according to the FIO_2 and TIDAL VOLUME setpoints. In CPAP mode, FIO_2 proportions are based on gas flowing at 1000ml/sec. The CPU makes any necessary flow corrections during the first one or two delivered breaths. Delivered FIO_2 is displayed in the LCD. The LCD display area for AIR/OXYGEN MIXER Control setpoint is on the bottom line, far right position. The AIR/OXYGEN MIXER Control setting display will blank when a SYSTEM FAILURE Alarm occurs. It will blink when an EXT AIR LOW/FAIL, O_2 LOW/FAIL, or FIO_2 Alarm occurs.

8.3.2 Control Settings and Status Indicators

When activated, the STATUS indicators are continuously displayed on the ventilator display. Table 8-2 describes the control settings and status indicators.

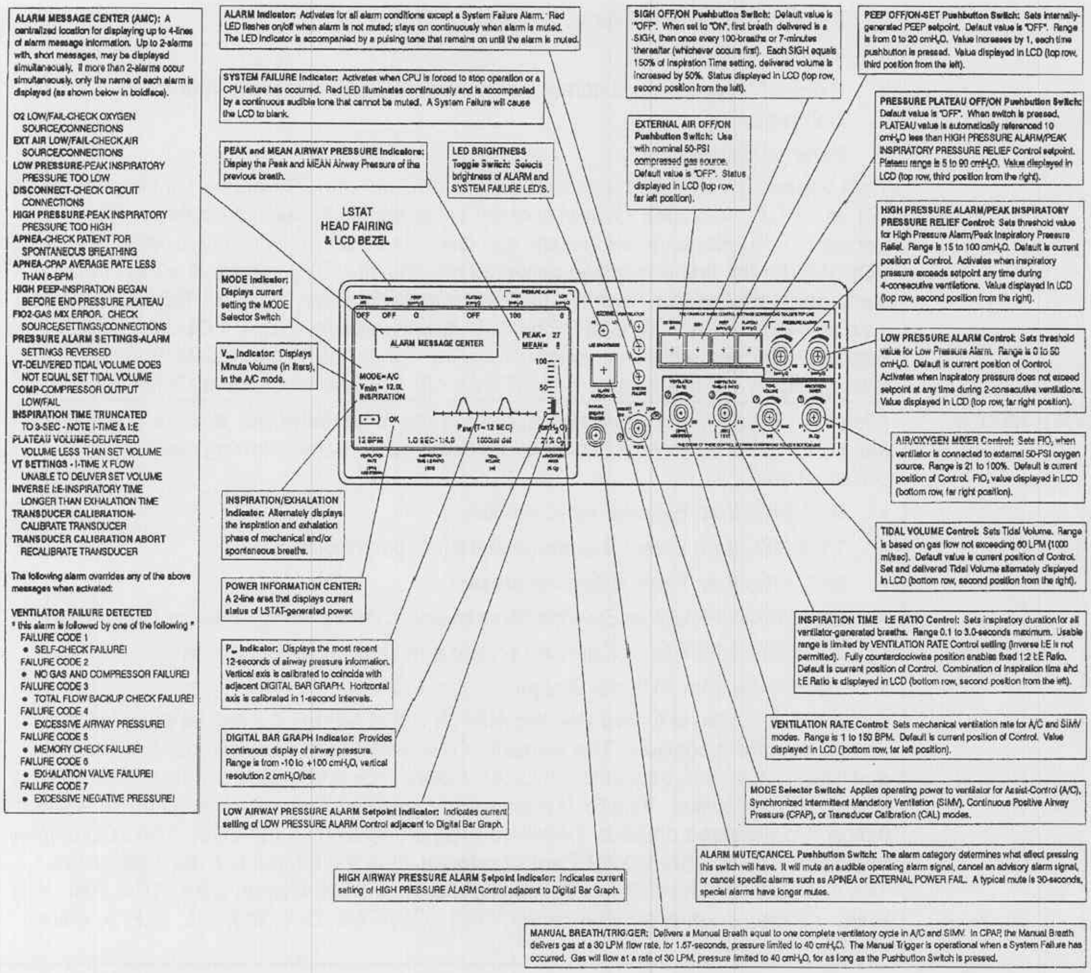

ALARM MESSAGE CENTER (AMC): A centralized location for displaying up to 4-lines of alarm message information. Up to 2-alarms with, short messages, may be displayed simultaneously. If more than 2-alarms occur simultaneously, only the name of each alarm is displayed (as shown below in boldface).
O2 LOW/FAIL-CHECK OXYGEN SOURCE/CONNECTIONS
EXT AIR LOW/FAIL-CHECK AIR SOURCE/CONNECTIONS
LOW PRESSURE-PEAK INSPIRATORY PRESSURE TOO LOW
DISCONNECT-CHECK CIRCUIT CONNECTIONS
HIGH PRESSURE-PEAK INSPIRATORY PRESSURE TOO HIGH
APNEA-CHECK PATIENT FOR SPONTANEOUS BREATHING
APNEA-CPAP AVERAGE RATE LESS THAN 6-BPM
HIGH PEEP-INSPIRATION BEGAN BEFORE END PRESSURE PLATEAU
FIO2-GAS MIX ERROR. CHECK SOURCE/SETTINGS/CONNECTIONS
PRESSURE ALARM SETTINGS-ALARM SETTINGS REVERSED
VT-DELIVERED TIDAL VOLUME DOES NOT EQUAL SET TIDAL VOLUME
COMP-COMPRESSOR OUTPUT LOW/FAIL
INSPIRATION TIME TRUNCATED TO 3-SEC - NOTE I-TIME & I:E
PLATEAU VOLUME-DELIVERED VOLUME LESS THAN SET VOLUME
VT SETTINGS - I-TIME X FLOW UNABLE TO DELIVER SET VOLUME
INVERSE I:E-INSPIRATORY TIME LONGER THAN EXHALATION TIME
TRANSDUCER CALIBRATION-CALIBRATE TRANSDUCER
TRANSDUCER CALIBRATION ABORT RECALIBRATE TRANSDUCER
The following alarm overrides any of the above messages when activated:
VENTILATOR FAILURE DETECTED
* this alarm is followed by one of the following *
FAILURE CODE 1
• SELF-CHECK FAILURE!
FAILURE CODE 2
• NO GAS AND COMPRESSOR FAILURE!
FAILURE CODE 3
• TOTAL FLOW BACKUP CHECK FAILURE!
FAILURE CODE 4
• EXCESSIVE AIRWAY PRESSURE!
FAILURE CODE 5
• MEMORY CHECK FAILURE!
FAILURE CODE 6
• EXHALATION VALVE FAILURE!
FAILURE CODE 7
• EXCESSIVE NEGATIVE PRESSURE!
ALARM Indicator: Activates for all alarm conditions except a System Failure Alarm. Red LED flashes on/off when alarm is not muted; stays on continuously when alarm is muted. The LED Indicator is accompanied by a pulsing tone that remains on until the alarm is muted.
SYSTEM FAILURE Indicator: Activates when CPU is forced to stop operation or a CPU failure has occurred. Red LED illuminates continuously and is accompanied by a continuous audible tone that cannot be muted. A System Failure will cause the LCD to blank.
PEAK and MEAN AIRWAY PRESSURE Indicators: Display the Peak and MEAN Airway Pressure of the previous breath.
LED BRIGHTNESS Toggle Switch: Selects brightness of ALARM and SYSTEM FAILURE LED'S.
LSTAT HEAD FAIRING & LCD BEZEL
MODE Indicator: Displays current setting the MODE Selector Switch
Vmin Indicator: Displays Minute Volume (in liters), in the A/C mode.
INSPIRATION/EXHALATION Indicator: Alternately displays the inspiration and exhalation phase of mechanical and/or spontaneous breaths.
POWER INFORMATION CENTER: A 2-line area that displays current status of LSTAT-generated power.
Paw Indicator: Displays the most recent 12-seconds of airway pressure information. Vertical axis is calibrated to coincide with adjacent DIGITAL BAR GRAPH. Horizontal axis is calibrated in 1-second intervals.
DIGITAL BAR GRAPH Indicator: Provides continuous display of airway pressure. Range is from -10 to +100 cmH2O, vertical resolution 2 cmH2O/bar.
LOW AIRWAY PRESSURE ALARM Setpoint Indicator: Indicates current setting of LOW PRESSURE ALARM Control adjacent to Digital Bar Graph.
HIGH AIRWAY PRESSURE ALARM Setpoint Indicator: Indicates current setting of HIGH PRESSURE ALARM Control adjacent to Digital Bar Graph.
SIGH OFF/ON Pushbutton Switch: Default value is "OFF". When set to "ON", first breath delivered is a SIGH, then once every 100-breaths or 7-minutes thereafter (whichever occurs first). Each SIGH equals 150% of Inspiration Time setting, delivered volume is increased by 50%. Status displayed in LCD (top row, second position from the left).
EXTERNAL AIR OFF/ON Pushbutton Switch: Use with nominal 50-PSI compressed gas source. Default value is "OFF". Status displayed in LCD (top row, far left position).
PEEP OFF/ON-SET Pushbutton Switch: Sets internally-generated PEEP setpoint. Default value is "OFF". Range is from 0 to 20 cmH2O. Value increases by 1, each time pushbutton is pressed. Value displayed in LCD (top row, third position from the left).
PRESSURE PLATEAU OFF/ON Pushbutton Switch: Default value is "OFF". When switch is pressed, PLATEAU value is automatically referenced 10 cmH2O less than HIGH PRESSURE ALARM/PEAK INSPIRATORY PRESSURE RELIEF Control setpoint. Plateau range is 5 to 90 cmH2O. Value displayed in LCD (top row, third position from the right).
HIGH PRESSURE ALARM/PEAK INSPIRATORY PRESSURE RELIEF Control: Sets threshold value for High Pressure Alarm/Peak Inspiratory Pressure Relief. Range is 15 to 100 cmH2O. Default is current position of Control. Activates when inspiratory pressure exceeds setpoint any time during 4-consecutive ventilations. Value displayed in LCD (top row, second position from the right).
LOW PRESSURE ALARM Control: Sets threshold value for Low Pressure Alarm. Range is 0 to 50 cmH2O. Default is current position of Control. Activates when inspiratory pressure does not exceed setpoint at any time during 2-consecutive ventilations. Value displayed in LCD (top row, far right position).
AIR/OXYGEN MIXER Control: Sets FIO2 when ventilator is connected to external 50-PSI oxygen source. Range is 21 to 100%. Default is current position of Control. FIO2 value displayed in LCD (bottom row, far right position).
TIDAL VOLUME Control: Sets Tidal Volume. Range is based on gas flow not exceeding 60 LPM (1000 ml/sec). Default value is current position of Control. Set and delivered Tidal Volume alternately displayed in LCD (bottom row, second position from the right).
INSPIRATION TIME I:E RATIO Control: Sets inspiratory duration for all ventilator-generated breaths. Range 0.1 to 3.0-seconds maximum. Usable range is limited by VENTILATION RATE Control setting (inverse I:E is not permitted). Fully counterclockwise position enables fixed 1:2 I:E Ratio. Default is current position of Control. Combination of inspiration time and I:E Ratio is displayed in LCD (bottom row, second position from the left).
VENTILATION RATE Control: Sets mechanical ventilation rate for A/C and SIMV modes. Range is 1 to 150 BPM. Default is current position of Control. Value displayed in LCD (bottom row, far left position).
MODE Selector Switch: Applies operating power to ventilator for Assist-Control (A/C), Synchronized Intermittent Mandatory Ventilation (SIMV), Continuous Positive Airway Pressure (CPAP), or Transducer Calibration (CAL) modes.
ALARM MUTE/CANCEL Pushbutton Switch: The alarm category determines what effect pressing this switch will have. It will mute an audible operating alarm signal, cancel an advisory alarm signal, or cancel specific alarms such as APNEA or EXTERNAL POWER FAIL. A typical mute is 30-seconds, special alarms have longer mutes.
MANUAL BREATH/TRIGGER: Delivers a Manual Breath equal to one complete ventilatory cycle in A/C and SIMV. In CPAP, the Manual Breath delivers gas at a 30 LPM flow rate, for 1.67-seconds, pressure limited to 40 cmH2O. The Manual Trigger is operational when a System Failure has occurred. Gas will flow at a rate of 30 LPM, pressure limited to 40 cmH2O, for as long as the Pushbutton Switch is pressed.
OFF OFF 0 OFF 100 8
ALARM MESSAGE CENTER
PEAK= 27
MEAN= 8
MODE=A/C
Vmin = 12.0L
INSPIRATION
OK
Paw(T=12 SEC)
(cmH2O)
100
50
0
12 BPM
1.0 SEC-1:4.0
1000ml del
21% O2

Figure 8-3. Ventilator Control Settings and Indicators

Table 8-2. Status Indicator Description

Indicator	Description
MODE	Based upon the **MODE** Switch setting, this indicator displays, respectively, **ASSIST, SIMV, CPAP**, or **CAL**. The mode Indicator display will blank when a SYSTEM FAILURE alarm occurs.
V_{min}	Displays Minute Volume (in liters) in the ACV mode, blanks during **SIMV, CPAP**, and **CAL** or when a PLATEAU VOLUME or SYSTEM FAILURE Alarm occurs.
INSPIRATION/EXHALATION	Alternately displays the "INSPIRATION" or "EXHALATION" phase of mechanical and/or spontaneous breaths in each operating mode, blanks during **CAL**. The **INSPIRATION/EXPIRATION** Indicator display will blank when a SYSTEM FAILURE Alarm occurs.

Indicator	Description
POWER INFORMATION CENTER (PIC)	Occupies a 2-line area in the LCD's lower left section. It illuminates when the MODE SELECTOR SWITCH is an any position except OFF and the CPU validates a usable source of power (see OPERATING POWER SELECTION & STOPPING) during the power check portion of self-check (see SELF-CHECK). The POWER INFORMATION CENTER display will blank when a SYSTEM FAILURE Alarm occurs. The POWER INFORMATION CENTER can display the following messages: Line 2: Battery icon "OK" or, Line 2: Battery icon "LOW" Battery icon "OK" acknowledges that there is adequate operating power for operation. Battery icon "LOW" tells users that there is less than the normal amount of LSTAT-generated power available, but it is still enough to allow the ventilator to properly operate.
PEAK AIRWAY PRESSURE	Displays the **PEAK AIRWAY PRESSURE** of the previous breath. The **PEAK AIRWAY PRESSURE** Indicator display will blank when a SYSTEM FAILURE Alarm occurs.
MEAN AIRWAY PRESSURE	Displays the **MEAN AIRWAY PRESSURE**. The Ventilator calculates **MEAN AIRWAY PRESSURE** to the following algorithm: $(\text{PIP-PEEP}) \text{ X } \frac{\text{I}}{\text{TOTAL CYCLE TIME}} + \text{PEEP}$ The **MEAN AIRWAY PRESSURE** Indicator display will blank when a SYSTEM FAILURE Alarm occurs.
DIGITAL BAR GRAPH	Provides continuous display of airway pressure. Its absolute range is from-10 to +100 cmH_2O. Increment markings appear every 10 cmH_2O, numerical markers appear at 0, 50, and 100 cmH_2O. Vertical resolution is 2 cmH_2O/bar. The **Digital BAR GRAPH** Indicator display will blank when a SYSTEM FAILURE Alarm occurs.
HIGH and LOW AIRWAY PRESSURE ALARM Setpoint Indicators	Indicators appear as small horizontal lines to the right of the **DIGITAL BAR GRAPH**. Setpoint indicators are positioned according to their respective alarm control settings and reposition whenever an alarm control is adjusted. Setpoint indicator vertical resolution is 2 cmH_20. The respective **HIGH** or **LOW AIRWAY PRESSURE ALARM** setpoint Indicator blinks when a **HIGH PRESSURE** or **LOW PRESSURE** Alarm is triggered and blanks when a SYSTEM FAILURE Alarm occurs.
P_{aw}	Represents a continuous and updating display of airway pressure. It display's the most recent 12-second period. Airway pressure amplitude along he vertical axis is calibrated to coincide with the adjacent digital bar graph. Markings along the horizontal axis represent 1-second intervals. The P_{aw} Indicator display will blank when a SYSTEM FAILURE Alarm occurs.

8.3.3 Ventilator Connectors

The ventilator connectors are shown in Figure 8-4 and described in Table 8-3. External air can be accepted through the external air ports located on both sides of LSTAT (Figure 8-6 and Figure 8-7).

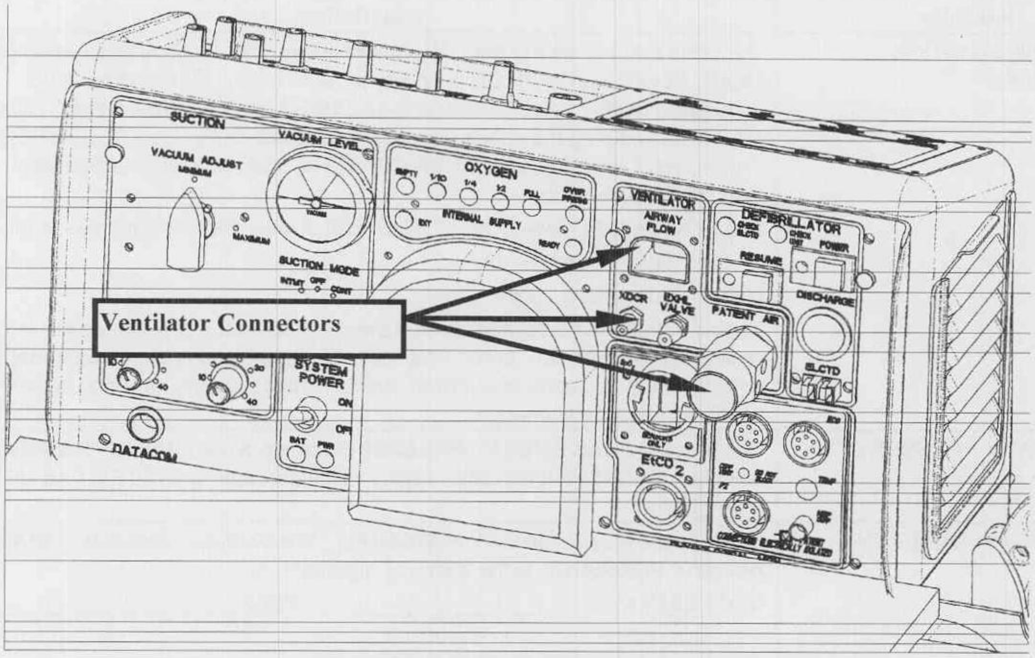

Ventilator Connectors
SUCTION
VACUUM ADJUST
VACUUM LEVEL
OXYGEN
SUCTION MODE
SYSTEM POWER
ON
OFF
DATACOM
VENTILATOR
AIRWAY FLOW
XDCR
EXHL VALVE
PATIENT AIR
DEFIBRILLATOR
RESUME
DISCHARGE
ELCTD
EtCO2

Figure 8-4. Ventilator Connectors

Table 8-3. Ventilator Connector Descriptions

Connector	Description
OXYGEN INLET	Nominal 50 PSI input, DISS, oxygen, male thread. Connects to output of oxygen cylinder pressure reducer (medical- grade only), PTLOX; or on-board aircraft generated source. Use the high-pressure hose, DISS Oxygen X DISS Oxygen, 6' long for interconnection.
AIR INLET	Nominal 50 PSI input, DISS air, male-thread. Connects to output of air cylinder pressure reducer (medical-grade only), or electric compressor (oil-less and filtered). Use the high-pressure hose, DISS Air X DISS Air, 6' long, for interconnection. Note: To protect the ventilator from dirt and condensate, use an Air Inlet Filter/Moisture Trap whenever external air is provided by an electric air compressor.
GAS OUTLET	Low pressure, 22mm male tapered connection. Connects to disposable ventilator circuit 22mm I.D. corrugated hose.
TRANSDUCER	Low pressure, fits 3/16" I.D. tubing. Connects ventilator pressure transducer to disposable ventilator circuit transducer hose. This connector is colored green.
EXHALATION VALVE	Low pressure, fits ¼" I.D. tubing. Connects ventilator exhalation valve control port to disposable ventilator circuit exhalation valve (Figure 8-5). This connector is clear aluminum in color.
FLOW SENSOR	The optional flow sensor connector provides a differential pressure measurement of both gas flow and volume. The displays for this sensor are only available through the LSTAT secondary display.

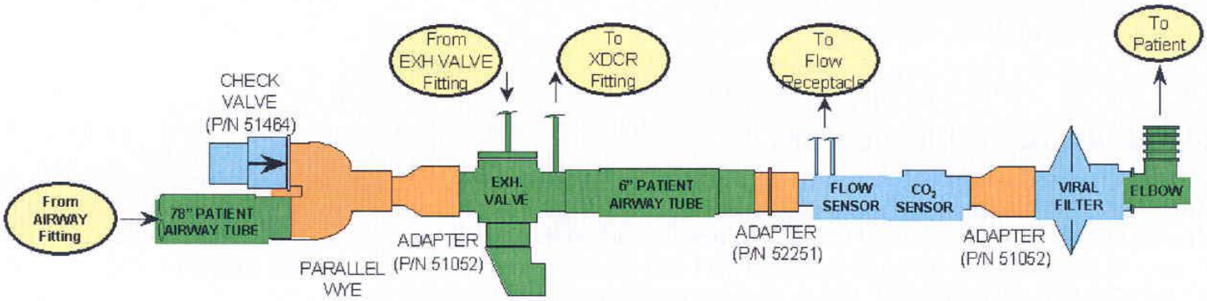

From AIRWAY Fitting
78" PATIENT AIRWAY TUBE
CHECK VALVE (P/N 51464)
PARALLEL WYE
ADAPTER (P/N 51052)
From EXH VALVE Fitting
EXH. VALVE
To XDCR Fitting
6" PATIENT AIRWAY TUBE
ADAPTER (P/N 52251)
To Flow Receptacle
FLOW SENSOR
CO_2 SENSOR
ADAPTER (P/N 51052)
VIRAL FILTER
ELBOW
To Patient

Figure 8-5. Ventilator Patient Circuit with Optional Flow Sensor

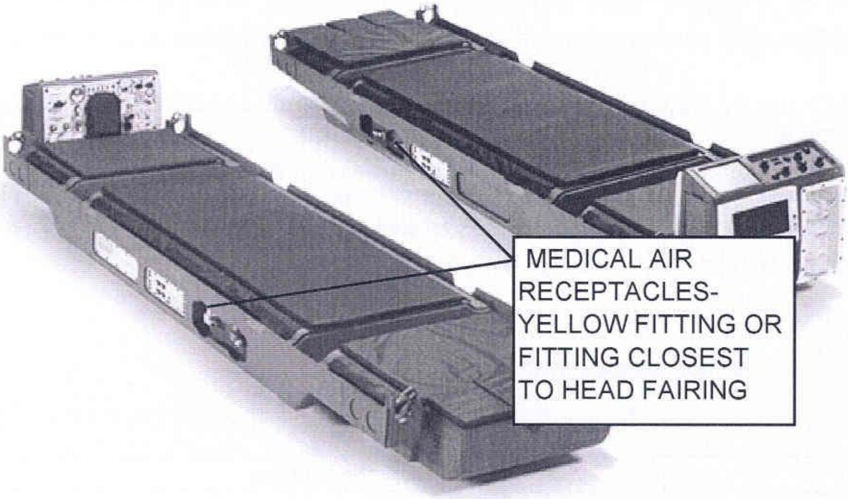

MEDICAL AIR RECEPTACLES- YELLOW FITTING OR FITTING CLOSEST TO HEAD FAIRING

Figure 8-6. External Air Ports

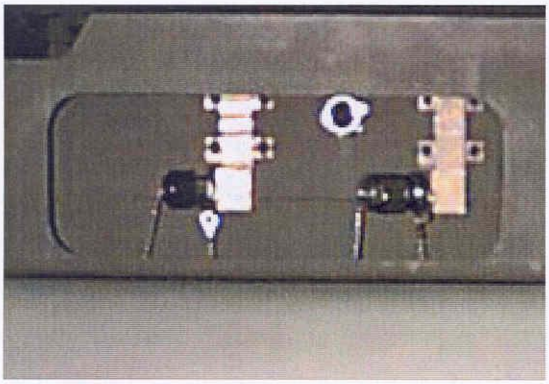


Figure 8-7. External Air, O2, and Inlet ports

8.4 Alarms and Indicators

The ventilator LCD display allocates up to 4-lines of alarm message information in a dedicated ALARM MESSAGE CENTER (AMC) (Figure 8-3). Each alarm is displayed on the display except for the ALARM Indicator and SYSTEM FAILURE LEDs that are located on the ventilator control panel. The ALARM Indicator illuminates, and alternately flashes ON and OFF whenever an alarm causing condition other than SYSTEM FAILURE occurs. An audible signal accompanies each alarm.

Alarms are categorized as **OPERATING** (Table 8-4), **NON-OPERATING** (Table 8-5), or **ADVISORY** (for detailed information on alarms see Section 4 ALARM FUNCTIONS). When the audible signal is muted during an OPERATING ALARM, the ALARM Indicator remains illuminated, but stops flashing, during the mute period. During an ADVISORY ALARM pressing **MUTE/CANCEL** turns the ALARM indicator OFF.

A NON-OPERATING ALARM **cannot** be muted or canceled. It will self cancel when its causing condition is corrected.

ADVISORY ALARMS may be muted **once**. The mute period will continue indefinitely or until its causing condition is corrected.

The alarm mute/cancel button will cancel an APNEA Alarm allowing the Ventilator to resume operation in the ACV, SIMV, or CPAP modes. Pressing the alarm mute/cancel button does not affect the AMC display (except for the APNEA message which is canceled).

A new alarm condition will always override a pre-existing "mute".

8.4.1 Operating Alarms

Operating alarms can be muted successively and allow continued operation.

Table 8-4. Operating Alarms

Alarm	Description
LOW PRESSURE	Initiates when PIP fails to exceed the LOW PRESSURE ALARM setpoint for two consecutive breaths and causes its LCD setpoint indicator to blink. When activated the AMC displays: LOW PRESSURE – PEAK INSPIRATORY PRESSURE TOO LOW or LOW PRESSURE. The AMC will blank if a non-operating alarm occurs. The setpoint indicator will alternately blink, with the HIGH PRESSURE Alarm LCD setpoint indicator, during a PRESSURE ALARM SETTINGS Alarm.
DISCONNECT	Initiates when a disconnect is sensed in the patient circuit. When activated the AMC displays: DISCONNECT - CHECK CIRCUIT CONNECTIONS or DISCONNECT. The AMC will blank if a non-operating alarm occurs.
HIGH PRESSURE	Initiates when PIP exceeds the HIGH PRESSURE Alarm setpoint for four consecutive breaths, or 2-seconds continuously, and causes its LCD setpoint indictor to blink. When activated the AMC displays: HIGH PRESSURE - PEAK INSPIRATORY PRESSURE TOO HIGH or HIGH PRESSURE. The AMC will blank if a non-operating alarm occurs. The setpoint indicator will alternately blink, with the LOW PRESSURE Alarm LCD setpoint indicator, during a PRESSURE ALARM settings Alarm.

Alarm	Description
APNEA	ACV and SIMV: Initiates when approximately 19-seconds have elapsed and no pressure deflections have been sensed. When activated the AMC displays: APNEA - CHECK PATIENT FOR SPONTANEOUS BREATHING or APNEA. CPAP: Initiates when no spontaneous breathing is detected for 10-seconds (based on a 30-second moving average). When activated the AMC displays: APNEA - CPAP AVERAGE RATE LESS THAN 6 BPM or APNEA. The AMC will blank if a non-operating alarm occurs.
HIGH PEEP	Initiates when the inspiratory cycle begins before end expiratory pressure plateaus. When activated the AMC displays: HIGH PEEP - INSPIRATION BEGAN BEFORE END PRESSURE PLATEAU or high peep. The AMC will blank if a non-operating alarm occurs.
0_2 LOW/FAIL	Initiates when low pressure is sensed from an external oxygen supply. When activated the AMC displays: O_2 LOW/FAIL - CHECK OXYGEN SOURCE/CONNECTIONS, O_2 LOW/FAIL or O_2. The AMC will blank if a non-operating alarm occurs.
EXT AIR LOW/FAIL	Initiates when low pressure is sensed from an external source of compressed air. When activated the AMC displays: EXT AIR LOW/FAIL - CHECK AIR SOURCE/CONNECTIONS, EXT AIR LOW/FAIL or EXT AIR. The AMC will blank if a non-operating alarm occurs.
FIO_2	Initiates when the oxygen component or the air component of THE AIR/OXYGEN MIXER is unable to meet is proportion of the gas mixture. When activated the AMC displays: FIO_2 GAS MIX ERROR. CHECK SOURCE/SETTINGS/CONNECTIONS or FIO_2. The AMC will blank if a non-operating alarm occurs.
PRESSURE ALARM SETTINGS	Initiates when the HIGH PRESSURE ALARM and LOW PRESSURE ALARM setpoints are reversed (i.e., low setpoint is set higher than the high setpoint). Both Control setpoint indicators, and both indicators adjacent to the DIGITAL BAR GRAPH, alternately blink during a PRESSURE ALARM SETTINGS Alarm. When activated the AMC displays: PRESSURE ALARM SETTINGS - ALARM SETTINGS REVERSED or PRESSURE ALARM SETTINGS. The AMC will blank if a non-operating alarm occurs.
V_t	Initiates when delivered tidal volume does not equal set tidal volume. When activated the AMC displays: V_t - DELIVERED TIDAL VOLUME DOES NOT EQUAL SET TIDAL VOLUME or V_t. The AMC will blank in the CPAP mode, or if a non-operating alarm occurs.
COMP	Initiates when the internal compressor output does not produce its intended contribution to tidal volume. When activated the AMC displays: COMP - COMPRESSOR OUTPUT LOW/FAIL or COMP. The AMC will blank if a non-operating alarm occurs.

8.4.2 Non-Operating Alarms

Non-operating alarms cannot be muted and do not allow operation to begin or continue.

Table 8-5. Non-Operating Alarms

Alarm	Description
INVERSE I:E	Initiates when inspiratory time becomes longer than expiratory time. When activated the AMC displays: INVERSE I:E - INSPIRATORY TIME LONGER THAN EXHALATION TIME or INVERSE I:E. The AMC will blank in the CPAP mode, or if a SYSTEM FAILURE Alarm occurs.
TRANSDUCER CALIBRATION	Initiates when the pressure transducer "zero" baseline exceeds +/- 1 cmH2O. When activated the AMC displays: TRANSDUCER CALIBRATION - CALIBRATE TRANSDUCER or TRANSDUCER CALIBRATION. The AMC will blank if a SYSTEM FAILURE Alarm occurs. If this alarm occurs during SELF- CHECK, it will become part of the VENTILATOR FAIL Alarm that it causes.
TRANSDUCER CALIBRATION ABORT	Initiates when the transducer calibration process is stopped prematurely. When activated the AMC displays: TRANSDUCER CALIBRATION ABORT - RECALIBRATE TRANSDUCER or TRANSDUCER CALIBRATION ABORT. The AMC will blank if a MEMORY CHECK or SYSTEM FAILURE Alarm occurs.
SYSTEM FAILURE	LED, illuminates when CPU is forced to shut down operation or a CPU failure has occurred. This alarm is usually related to a hardware problem and will cause the LCD to blank, so no error code will be displayed.

Alarm	Description
VENTILATOR FAIL	Initiates when any one of seven ventilator failure causing conditions occur. These conditions will not cause the LCD to blank, and some may be operator correctable. A VENTILATOR FAIL Alarm will cause the alarm led to illuminate. It will not cause the SYSTEM FAILURE LED to illuminate. The LCD will display: VENTILATOR FAILURE DETECTED followed by FAILURE CODE# (a number from 1 to 7), and an abbreviated description of the failure.

8.4.3 Advisory Alarms

Advisory alarms permit continued operation and can be muted once.

Table 8-6. Advisory Alarms

Alarm	Description
INSPIRATION TIME TRUNCATED TO 3-SEC.	Initiates when control settings would cause inspiration time to exceed 3-seconds. It is disabled in the CPAP mode. When activated the AMC displays: INSPIRATION TIME TRUNCATED TO 3-SEC - NOTE I-TIME & I:E. The AMC will blank if a non-operating alarm occurs. A SIGH breath that would exceed 3.0 seconds is truncated but will not activate this alarm.
PLATEAU VOLUME	Initiates when delivered PRESSURE PLATEAU tidal volume is less than set tidal volume by more than 5%. When activated the AMC displays: PLATEAU VOLUME - DELIVERED VOLUME LESS THAN SET VOLUME. The AMC will blank in the CPAP mode, or if a non-operating alarm occurs.
V_T SETTINGS	Initiates whenever the sum of the flows of the selected gases would exceed a flow rate of 60 liters per minute (LPM). When activated the AMC displays: V_T SETTINGS - I - TIME X FLOW UNABLE TO DELIVER SET VOLUME or V_T SETTINGS. The AMC will blank in the CPAP mode.
PREVENTATIVE MAINTENANCE	Initiates after 2,000-hours of cumulative use, or 12-months, whichever occurs first. When activated the AMC displays: PREVENTATIVE MAINTENANCE DUE - CONTACT CUSTOMER SERVICE. The AMC will blank if a non-operating alarm occurs.
EXTENDED NON-USE STORAGE	Initiates at power-up after 6-months of continuous non-use/storage has occurred. When activated the AMC displays: EXTENDED NON-USE/STORAGE - TEST BEFORE PATIENT USE. The AMC will blank if a non-operating alarm occurs.
TOTAL FLOW BACKUP	Initiates when the backup flow sensor detects the sum of the flows (O2, Air, and internal compressor) exceeding set flows by +/- 50% for five consecutive breaths. There must be a total flow rate of at least 10 LPM and a total tidal volume of at least 200ml for this alarm to operate. When activated, the AMS displays: TOTAL FLOW BACKUP – CONTACT CUSTOMER SERVICE. The AMC will blank if a non-operating alarm occurs.

8.4.4 Alarm Muting and Canceling

Press the ALARM MUTE/CANCEL button to deactivate the audible portion of an existing operating alarm for a 30-second period.

8.5 Operating Power Selection and Stopping

The Ventilator is designed to operate from the LSTAT power supply. The Mode Selector switch acts as the master power switch for the ventilator.

The power information center (PIC) occupies a 2-line area in the LCD's lower left section. It illuminates when the mode Selector Switch is in any position except off and the CPU validates that there is adequate incoming power.

8.6 Ventilator Set-Up, Self-Check, and Transducer Calibration

8.6.1 Set-Up

The Ventilator is easily configurable to suit most applications. Additional hoses, fittings and adapters may be required for particular uses.

Test all configurations for correct operation prior to patient connection.

8.6.2 Self-Check

The Ventilator undergoes a self-checking process every time its MODE Selector Switch is turned from "OFF" to ACV, SIMV, or CPAP; or from CAL to ACV, SIMV OR CPAP. After the initial SELF-CHECK is performed, self-checking is not repeated if the operator turns the MODE Selector Switch to another operating mode position.

The self-check process consists of interaction between the Ventilator's microprocessor and peripheral circuitry to verify power status, memory check, and pressure transducer calibration and control panel settings.

WARNING

DO NOT CONNECT PATIENT CIRCUIT TO PATIENT DURING SELF-CHECK.

This insures that the transducer connection is open to ambient atmosphere. Ignoring this requirement could cause the self-check process to sense a residual airway pressure. Current information is compared to previous calibration information stored in memory. Accordingly, any residual pressure would result in a false reading leading to a self-check failure.

NOTE

If external oxygen and/or external compressed gas is connected, each gas pressure must be at least 40-PSI (±2-PSI) at the time SELF-CHECK is performed.

If self-check completes successfully, ventilator operation begins immediately following SELF-CHECK.

If the Ventilator fails SELF-CHECK, a VENTILATOR FAIL alarm will occur and the following is displayed in the alarm message center:

FAILURE CODE 1
SELF-CHECK FAILURE!

Do the following:
Return the MODE Selector switch to its off position and then repeat this procedure. If SELF-CHECK fails again, contact qualified service personnel - DO NOT ATTEMPT PATIENT USE.

SELF-CHECK will automatically alert if the pressure transducer calibration "zero" baseline exceeds ± 1 cmH2O from its last calibration. A TRANSDUCER CALIBRATION Alarm activated during SELF-CHECK will cause an audible tone and the AMC to display:

TRANSDUCER CALIBRATION - CALIBRATE TRANSDUCER VENTILATOR FAILURE DETECTED
FAILURE CODE 1 – SELF-CHECK FAILURE!

OR, if SELF-CHECK alarm is not related to the Transducer Calibration:

VENTILATOR FAILURE DETECTED
FAILURE CODE 1 – SELF-CHECK FAILURE!

8.6.3 Transducer Calibration

NOTE

It is recommended that the Ventilator be calibrated before each use.

The PIC will display information pertinent to operating power in addition to the AMC messages displayed when calibrating the transducer.

A TRANSDUCER CALIBRATION ABORT Alarm will occur if the MODE Selector Switch is turned to an operating mode position before CAL is completed. The CAL procedure must be restarted by turning the MODE Selector Switch to any position other than CAL, and then returning it to CAL, and repeating the process described in steps 1 and 2. When activated the AMC displays: "TRANSDUCER CALIBRATION ABORT-RECALIBRATE TRANSDUCER" or "TRANSDUCER CALIBRATION ABORT". The AMC will blank if a SYSTEM FAILURE Alarm occurs.

The Ventilator includes built-in altitude compensation. Once a TRANSDUCER CALIBRATION has been performed, changes in altitude will have no effect upon pressure related performance.

WARNING

TRANSDUCER CALIBRATION, LIKE SELF-CHECK, MUST BE PERFORMED WITH THE DISPOSABLE VENTILATOR CIRCUIT DISCONNECTED FROM THE PATIENT. THIS INSURES THAT THE TRANSDUCER CONNECTION IS OPEN TO AMBIENT ATMOSPHERE. IGNORING THIS REQUIREMENT WOULD ALLOW THE PROCEDURE TO SENSE ANY RESIDUAL AIRWAY PRESSURE IN THE PATIENT CIRCUIT. THE RESIDUAL PRESSURE BECOMES THE NEW CALIBRATION REFERENCE (ALBEIT A FALSE REFERENCE), WHICH WILL INCREASE YOUR PATIENT'S WORK-OF-BREATHING BY THE RESIDUAL AMOUNT.

The disposable ventilator circuit connects to a pressure-sensing element (transducer) in the ventilator. The transducer, in turn, provides a stream of data to the Ventilator's microprocessor. Transducer calibration is stored in a serial, non-volatile EEPROM memory. This information is updated automatically during SELF-CHECK, then every five minutes thereafter through the ventilator's AUTO CAL function, or, the user can manually update it. Transducer calibration is essential for correct operation.

The TRANSDUCER CALIBRATION process calibrates the ventilator's internal pressure transducer to atmospheric pressure. During operation, the ventilator's microprocessor will respond according to pressure signals from the transducer which are compared to its control panel settings.

Automatic Calibration (AUTO CAL):

During ventilator operation, the ventilator performs an automatic calibration of its pressure transducer every five minutes. This process maintains a consistent transducer baseline over a wide temperature range to assure display, monitoring, and triggering accuracy. If the baseline drifts significantly since the prior AUTO CAL was performed, or the baseline is unstable, the ventilator will retry AUTO CAL one minute later. If AUTO CAL fails again, a VENTILATOR FAILURE Alarm, CODE 7 is activated to assure patient safety.

Manual Calibration:

1. Set mode Selector Switch to CAL. The AMC will display: "Calibration...Please Wait". Then, "MODE = CAL" will appear.

3. Calibration will take approximately 3-seconds. When finished, the AMC display will change to: "MODE = CAL OK".

A TRANSDUCER CALIBRATION ABORT Alarm will occur if the MODE Selector Switch is turned to an operating mode position before CAL is completed. The CAL procedure must be restarted by turning the MODE Selector Switch to any position other than CAL, and then returning it to CAL, and repeating the process described in steps 1, and 2 above. When activated the AMS displays: TRANSDUCER CALIBRATION ABORT. The AMC will blank if a SYSTEM FAILURE Alarm occurs.

8.7 User Programs

The Ventilator contains a USER PROGRAMS menu that allows certain operating characteristics to be changed. Some changes can be stored in the Ventilator's memory - temporary changes are not. Program changes that get stored in memory apply each time the ventilator is operated or, until the user makes a new program change affecting that particular characteristic. Temporary changes are not stored in memory and will last until ventilator power is turned OFF. User programmable/ selectable characteristics are LCD Backlight threshold default, LCD Contrast default, Trigger Level Sensitivity, Set Spontaneous Flow, Demonstration Mode (DEMO), and TEST BACKUP VENTILATOR.

The bottom line of each menu in user programs contains the following information:

"#### Hrs." - where "####" represents cumulative hours of operation since the last Preventative Maintenance was performed.

"### Dys" - where "###" represents cumulative days since the last Preventative Maintenance was performed.

"Version #.##" - where "#.##" indicates the software version.

To enter the User Programs Menu:

1. Simultaneously press MUTE, and MANUAL BREATH/TRIGGER button while turning the MODE control Switch to ASSIST, SIMV, CPAP, or CAL.
2. Follow on screen prompts.
3. Press button adjacent to make your selections.
4. Press button adjacent to "EXIT" to leave USER PROGRAMS menu and return to selected mode of operation: A/C, A/C DEMO, SIMV, SIMV DEMO, CPAP, CPAP DEMO, CAL.

Changes can be stored in memory by pressing the button adjacent to the SAVE prompt or temporarily used during the current operating cycle.

5. Press SAVE after each selection to store in memory. If "SAVE" is **not** pressed, the previously stored setpoint remains.

Set Display Backlight Threshold Default

Sets the LCD's backlight setpoint. When programmed, it defaults to current ambient lighting conditions to assure adequate display illumination during operation.

Set Display Contrast Default

Controls the LCD's contrast setpoint. Depending upon viewing comfort, users may choose to increase or decrease color contrast between activated LCD pixels and their background. Any increase or decrease to the setpoint is seen on the LCD.

Set Trigger Level Sensitivity

The Ventilator includes preset trigger sensitivity default. Preset trigger sensitivity default is set between 1.5 and 2.0 cmH_2O below end pressure. Triggering sensitivity determines how much negative deflection a spontaneous breathing patient must generate before the Ventilator initiates a mechanical breath or demand flow. In the Ventilator, triggering sensitivity is both automatic and PEEP compensated.

During operation the Ventilator's preset trigger looks for the next spontaneous breath to reach its trigger threshold. For whatever reason, if a spontaneous breath is in process when the trigger is activated, the following conditions prevail:

If the patient's inspiratory pressure has not reached the trigger threshold, the Ventilator will trigger when the threshold is reached.

If the patient's inspiratory pressure has exceeded the trigger threshold, the Ventilator will wait until the next spontaneous inspiration reaches threshold before triggering.

The USER PROGRAM allows Trigger Level Sensitivity to be temporarily changed until operating power is turned off. It is adjustable from 1.0 to 6.0 cmH_2O in 0.5 cmH_2O increments. For spontaneous breaths occurring in SIMV and CPAP, the sensitivity cannot be set below 2 cmH_2O. Sensitivity adjustments to 2 cmH_2O, or higher, will affect all breaths. Adjustments made below 2 cmH_2O will only affect mandatory breaths. New settings cannot be saved in memory. Once operating power is turned "OFF" Trigger Level Sensitivity is returned to its default value.

NOTE

Under most operating conditions the Ventilator's default trigger sensitivity should be used. Users are cautioned to carefully consider their operating environment before selecting a different Trigger Level Sensitivity. If 1.0 cmH_2O is selected, motion artifact many cause false triggering of breaths. Conversely, selecting a sensitivity above 2.0 cmH_20 to compensate for excessive motion artifact, or physiological conditions, can cause excessive inspiratory work- of-breathing.

Set Spontaneous Flow

The Ventilator's default Spontaneous Flow is 60 LPM. This USER PROGRAM allows Spontaneous Flow (for use in SIMV or CPAP) to be temporarily changed until operating power is turned OFF. It is adjustable from 10 to 60 LPM in 5 LPM increments. New settings cannot be saved in memory. Once operating power is turned "OFF", Spontaneous Flow is returned to its default state.

WARNING

DEMO MODE IS NOT FOR PATIENT USE. ONCE OPERATING POWER IS TURNED "OFF" DEMO MODE IS CANCELED.

Demonstration Mode (DEMO)

Permits users to operate this device in a mode that is quite helpful for demonstration/training purposes. DEMO mode allows user's to make settings, adjustments, trigger alarms, and view simulation waveform on the Ventilator 's LCD. DEMO mode does not allow Disconnect Alarm activation or Proximal Pressure Transducer operation.

Test Backup Ventilator

Permits user to test the BACKUP VENTILATOR and MANUAL TRIGGER. Activating the BACKUP VENTILATOR will cause it to function as described in the section entitled BACKUP VENTILATOR. To leave the BACKUP VENTILATOR function and return to normal operation, turn the MODE Control Switch to "OFF" then "ON" to desired operating mode.

8.8 Ventilator Operation

1. Toggle the LSTAT SYSTEM POWER switch to the "ON" position.
2. Turn the MODE switch to CAL mode to perform Ventilator calibration.

If the Electronics Display shows: MODE = CAL OK, then ventilator operations can proceed.

3. If external oxygen will to be used, then turn the select % O_2 switch to the desired setting.
4. If external air is connected, observe ON is displayed on ventilator display.
5. Select the Operating mode; ACV (ASSIST), SIMV or CPAP.
6. Set VENTILATION RATE.
7. Set INSPIRATION TIME. If your protocol calls for use only at 1:2 I:E RATIO, then this step can be skipped.
8. Set TIDAL VOLUME.
9. Set the AIR/OXYGEN MIXER for and FIO_2 between 21 and 100. If using internal oxygen, or with 100% oxygen, the air/oxygen mixer control remains either fully counterclockwise or fully clockwise.
10. Connect Ventilator Patient Circuit (Figure 8-5) to ventilator connector panel (Figure 8-4).
11. If the Flow Sensor is installed, press the FLOW ZERO button momentarily to calibrate the Flow Sensor.

NOTE

After SELF-CHECK is completed, ventilation cycling begins automatically. The INSPIRATION/EXHALATION Indicator will toggle accordingly during the inspiratory and expiratory cycles of each ventilation.

When cycling begins, the DISCONNECT alarm will activate. This alarm will remain active until the disposable ventilator circuit is connected to the patient and the pressure transducer detects a pressure rise during the next ventilator generated breath, or the ALARM MUTE/CANCEL Pushbutton Switch is pressed.

The ventilator can operate in the following modes:

ASSIST-CONTROL VENTILATION with or without PEEP, with or without SIGH

ASSIST-CONTROL VENTILATION with or without PEEP, with or without PRESSURE PLATEAU

SYNCHRONIZED INTERMITTENT MANDATORY VENTILATION with or without PEEP, with or without SIGH

SYNCHRONIZED INTERMITTENT MANDATORY VENTILATION with or without PEEP, with or without PRESSURE PLATEAU

CONTINUOUS POSITIVE AIRWAY PRESSURE with or without PEEP

CONTROL VENTILATION (apnea backup of ACV, SIMV, and CPAP)

CONTROL VENTILATION (backup ventilator)

WARNING

FUNCTIONS WHICH ARE DEPENDENT UPON ACCURATE PRESSURE READINGS SHOULD ONLY BE USED IN CONJUNCTION WITH A PROTECTED AIRWAY. THIS WILL PREVENT "LEAKS" FROM DISTORTING PRESSURE SIGNALS. DO NOT USE PRESSURE DEPENDENT FUNCTIONS WITH AN UNPROTECTED AIRWAY. THIS APPLIES PRIMARILY TO USE WITH UNCUFFED ENDOTRACHEAL TUBES, UNCUFFED TRACHEOSTOMY TUBES AND RESUSCITATION MASKS WHERE THE FACE-TO-MASK-SEAL INTEGRITY IS FREQUENTLY AND TYPICALLY COMPROMISED.

NOTE

ACV, SIMV, and CPAP ventilations are continuously monitored. Should apnea occur in one of these modes, the Ventilator's microprocessor will activate applicable alarms and initiate control

NOTE

Control panel settings may be adjusted at any time. In normal use, adjustments are typically made immediately following SELF-CHECK, however, the 1:2 I:E RATIO and extents for FIO_2 and PRESSURE ALARMS may be preset. Some high demand control settings at ventilator startup may case the ventilator to trigger failure alarms. Always set the ventilator to moderate settings at startup.

Preset trigger sensitivity default is set between 1.5 and 2.0 cmH2O below end pressure. Triggering sensitivity determines how much negative deflection a spontaneously breathing patient must generate before the ventilator initiates a mechanical breath or demand flow. Triggering sensitivity is both automatic and PEEP compensated. To change trigger sensitivity, or Spontaneous Flow for SIMV and CPAP, see section 8.7 USER PROGRAMS.

During operation the ventilator preset trigger looks for the next spontaneous breath to reach its trigger threshold. For whatever reason, if a spontaneous breath is in process when the trigger is activated, the following conditions prevail:

If the patient's inspiratory pressure has not reached the trigger threshold, the ventilator will trigger when the threshold is reached.

If the patient's inspiratory pressure has exceeded the trigger threshold, the ventilator will wait until the next spontaneous inspiration reaches threshold before triggering.

NOTE

The ventilator includes built-in altitude compensation. Once you've preformed a TRANSDUCER CALIBRATION, changes in altitude will have not effect upon pressure-related performance.

8.8.1 Assist-Control Ventilation (ACV)

In ACV (ASSIST on the Control Panel), the Ventilator is configured to deliver a minimum ventilatory rate, preset inspiration time and preset tidal volume. Patient-initiated breaths, sensed by negative pressure deflection, cause the Ventilator to trigger "assisted" ventilation that is equal to its INSPIRATION TIME and TIDAL VOLUME settings. Controlled ventilation's are delivered when there are no spontaneous respirations or the patient's spontaneous ventilation rate attempts to fall below the current VENTILATION RATE setting. If this occurs, controlled ventilations are delivered at the VENTILATION RATE, INSPIRATION TIME and TIDAL VOLUME settings.

Should the patient become apneic in the ACV mode, the Ventilator will activate its APNEA Alarm and automatically begin controlled ventilation's at its current VENTILATION RATE/INSPIRATORY TIME/TIDAL VOLUME control settings or 12 ventilation's per minute/INSPIRATORY TIME/TIDAL VOLUME control settings, whichever is greater (see section 8.8.4 CONTROL VENTILATION DURING APNEA; APNEA DURING ACV OR SIMV OPERATION).

ACV operation is permitted in combination with PEEP and/or SIGH or PEEP an/or PRESSURE PLATEAU (SIGH will become disabled whenever PRESSURE PLATEAU is selected).

For ASSIST CONTROL Ventilation:

1. Turn the mode Selector Switch to ASSIST.

   Allow self-check tests to complete. Perform transducer calibration, if required (section 8.6.3). DO NOT connect disposable patient circuit to patient during SELF-CHECK.

   When SELF-CHECK is completed, ACV cycling begins automatically. The INSPIRATION/EXHALATION Indicator will toggle accordingly during the inspiratory and expiratory cycles of each ventilation.

NOTE

When ACV cycling begins, the DISCONNECT Alarm will activate. This alarm will remain active until the disposable ventilator circuit is connects to the patient (see Step 3, below) and the pressure transducer detects a pressure rise during the next ventilator generated breath, or the ALARM MUTE/CANCEL Pushbutton Switch is pressed.

2. Adjust VENTILATION RATE, INSPIRATION TIME I:E RATIO, TIDAL VOLUME, AIR/OXYGEN MIXER, LOW and HIGH AIRWAY PRESSURE ALARM Control settings, as required. If LOW and HIGH airway pressure alarms are not used, set their respective controls to 0 and 100.
3. Attach disposable ventilator circuit to patients endotracheal or tracheostomy tube. Spontaneous breathing should cause the ventilator to trigger an assisted breath and cancel the DISCONNECT alarm. A ventilator-generated controlled breath will also cause the DISCONNECT Alarm to cancel. The INSPIRATION/EXHALATION indicator will continue to toggle during the inspiratory and expiratory cycles of each ventilation.
4. If PEEP is required, repeatedly press PEEP button until desired setting appears in display.
5. If SIGH is required, press SIGH button. SIGH ventilation's are delivered once every 100 ventilation's or 7-minutes, whichever occurs first. Each SIGH ventilation equals 150% of the INSPIRATION TIME setting, which increases delivered volume by 50%. As a safety precaution, the Ventilator does not allow the inspiratory portion of a SIGH breath to exceed 3-seconds.
6. Press PLATEAU button if ACV operation with PRESSURE PLATEAU is required. SIGH is automatically disabled (OFF) when PLATEAU is selected. PRESSURE PLATEAU limits peak airway pressure to the PLATEAU level for the duration of inspiratory cycle. The PRESSURE PLATEAU value is automatically referenced to 10 cmH_2O below the HIGH PRESSURE ALARM/PEAK INSPIRATORY PRESSURE RELIEF Control Setting.

8.8.2 Synchronized Intermittent Mandatory Ventilation (SIMV)

SIMV permits patients to breathe spontaneously while periodically receiving ventilator-generated assisted breaths. Microprocessor control of the disposable ventilator circuits' expiration valve determines which breaths are spontaneously entrained and which are mechanically delivered. FIO_2 is determined by the AIR/OXYGEN MIXER setting. Spontaneously breathing patients are allowed to entrain breathing gas, assuming the entire work-of-breathing for each spontaneous breath, at their own rate/inspiratory time. Assisted breaths are delivered as determined by the VENTILATION RATE, INSPIRATORY TIME/I:E RATIO, and TIDAL VOLUME control settings. Assisted breaths are synchronized tot he patients ventilatory effort. However, if the patient does not breathe within the assisted breath "time window", a controlled breath is delivered to ensure that the prescribed number of mandatory breaths are received.

Should the patient become apneic in the SIMV mode, the Ventilator will activate its APNEA alarm and automatically begin controlled ventilation's at its current VENTILATION RATE/INSPIRATORY TIME/TIDAL VOLUME control settings or 12 ventilation's per minute/INSPIRATORY TIME/TIDAL VOLUME control settings, whichever is greater.

SIMV operation is permitted in combination with PEEP and/or SIGH, or PEEP and/or PRESSURE PLATEAU (SIGH will become disabled whenever PRESSURE PLATEAU is selected). Perform the following to initiate SIMV operation.

1. Turn mode Selector Switch to SIMV. Allow SELF-CHECK tests to complete. Perform TRANSDUCER CALIBRATION if required (section 8.6.3 Transducer Calibration).

   DO NOT connect disposable patient circuit to patient during SELF-CHECK.

   When SELF-CHECK is completed, SIMV cycling begins automatically. The INSPIRATION/EXHALATION indicator will toggle accordingly during the inspiratory and expiratory cycles of each ventilation.

NOTE

When SIMV cycling begins, the DISCONNECT ALARM will activate. This alarm will remain active until the disposable ventilator circuit is connected to the patient (see Step 3 below) and the pressure transducer detects a pressure rise during the next ventilator generated breath, or the ALARM MUTE/CANCEL Pushbutton Switch is pressed.

2. Adjust the ventilation rate (SIMV rate), inspiration time/I:E ratio, tidal volume, air/oxygen mixer, low and high airway pressure alarm Control settings as required. If low and high airway pressure Alarms are not used, then set their respective controls to 0 and 100.

> NOTE
>
> During SIMV operation, mandatory breaths are delivered according to the Ventilator's VENTILATION RATE, INSPIRATION TIME and TIDAL VOLUME control settings. When the mandatory breath is scheduled, the Ventilator's trigger becomes momentarily armed so that it may synchronize with the patients next inspiration. If there is no inspiratory effort during this period, a controlled breath is delivered regardless of patient effort.
>
> During SIMV operation, mandatory breaths are delivered at the INSPIRATION TIME and TIDAL VOLUME settings.

3. Attach disposable ventilator circuit (Figure 8-5) to patients endotracheal or tracheostomy tube. Spontaneous breathing should cause the ventilator to trigger an assisted breath and cancel the DISCONNECT Alarm. A ventilator-generated controlled breath will also cause the DISCONNECT Alarm to cancel. The inspiration/exhalation Indicator will continue to toggle during the inspiratory and expiratory cycles of each ventilation.
4. If PEEP is required, repeatedly press PEEP button until desired setting appears in the display.
5. Press SIGH button if SIMV operation with SIGH is required. SIGH ventilations are delivered once every 100 ventilations or 7-minutes, whichever occurs first. Each SIGH ventilation equals 150% of the INSPIRATION TIME setting, which increases delivered volume by 50%. As a safety precaution, the Ventilator does not allow a SIGH breath to exceed 3-seconds.
6. Press PLATEAU Pushbutton Switch if SIMV operation with PRESSURE PLATEAU is required. SIGH is automatically disabled (OFF) when PLATEAU is selected. PRESSURE PLATEAU limits peak airway pressure to the PLATEAU level for the duration of an inspiratory cycle. The PRESSURE PLATEAU value is automatically referenced 10 cmH_2O below the HIGH PRESSURE ALARM/PEAK INSPIRATORY PRESSURE RELIEF Control Setting.

8.8.3 Continuous Positive Airway Pressure (CPAP)

CPAP operation is similar to SIMV with PEEP, except the mandatory rate is "zero". There are no assisted ventilations. The VENTILATOR RATE becomes "zero" and its setpoint indicator blanks. CPAP permits the patient to breathe spontaneously with PEEP. Each spontaneous breath causes a negative pressure deflection. When the trigger point is reached (2.0 cmH_2O below end pressure), Ventilator causes gas to flow at a default rate of 60 LPM until a back pressure of PEEP +5 cmH_2O is sensed (unconditional end-of-inspiration) or, 3-seconds have elapsed (time out), whichever occurs first. The Spontaneous Flow rate can be changed to a lesser flow rate, for current use, until operating power is turned off FIO_2 is equal to the AIR/OXYGEN MIXER setpoint. PRESSURE PLATEAU and SIGH are disabled (OFF) during CPAP operation.

An APNEA alarm activates when there is no spontaneous breathing for 10-seconds (based on a 30-second moving average). If the spontaneous breathing rate falls to 6 BPM (or less), control ventilation during APNEA will begin.

8.8.4 Control Ventilation During Apnea

When apnea is detected during ACV, SIMV, or CPAP operation, the Ventilator's microprocessor generates an APNEA Alarm and initiates controlled ventilation breathing to protect your patient. Control settings that were displayed prior to APNEA will remain displayed, but ignored, during these CONTROL VENTILATIONS.

Press the ALARM MUTE/CANCEL button to cancel the APNEA Alarm and stop CONTROL VENTILATION DURING APNEA. ACV, SIMV, or CPAP operation will continue with current control panel settings.

APNEA during ACV or SIMV operation

Controlled ventilation occurs when the period between positive and/or negative pressure deflections (spontaneous and/or Ventilator generated ventilation's) exceeds 19-seconds minus INSPIRATION TIME setting. Monitoring the APNEA is disabled during an INVERSE I:E Alarm.

The ventilator will provide the patient one of the following, whichever offers the highest ventilation rate:

Control panel settings for VENTILATION RATE, INSPIRATION TIME and TIDAL VOLUME, or

A default ventilation rate or 12 ventilation's per minute and the control panel INSPIRATION TIME and TIDAL VOLUME Control settings.

NOTE

To prevent a potential lockout of the APNEA backup, the Ventilator will create a 1:2 I:E ratio at the onset of APNEA if its current inspiratory time setting would result in an Inverse I:E condition.

APNEA during CPAP operation:

Controlled ventilation occurs when no spontaneous breathing is detected for 10-seconds. Controlled ventilations will have the following characteristics:

Mechanical rate = 12 breaths per minute.

I:E ratio = 1:2

Tidal volume = Will vary with patient. The Ventilator will deliver gas at a flow rate of 30 liters per minute until a peak inspiratory pressure of 40 cmH$_2$0 is reached.

8.8.5 Positive End Expiratory Pressure (PEEP)

The Ventilator is capable of internally controlling PEEP. A separate PEEP valve is not required and must not be added to the disposable patient circuit. The PEEP function provides a means of converting the transducer calibration pressure reference from atmospheric pressure to atmospheric pressure + PEEP pressure. PEEP may be used during ACV, SIMV, or CPAP operation.

When the ventilator is turned on, PEEP has a default value of 0 (OFF). A PEEP value can be manually entered using the PEEP OFF/ON-SET button. To set a value of PEEP, simply press the PEEP OFF/ON-SET button. Each time this switch is pressed, the value of PEEP will increase by 1 cmH$_2$O. A maximum PEEP value of 20 cmH$_2$O is possible. Pressing the PEEP OFF/ON-SET button when a current value of 20 exists, turns the value to 0. The PEEP setpoint value can be made to scroll upwards by putting continuous pressure on the PEEP OFF/ON-SET button until the desired value is reached.

Default trigger sensitivity is referenced to end pressure and will trigger between 1.5 to 2.0 cmH$_2$O below the end pressure value.

The Ventilator's CPU monitors PEEP. If PEEP pressure attempts to rise during its plateau, the Ventilator causes the exhalation valve to open, allowing pressure to fall to zero. Should an inspiration cycle begin before end pressure plateaus, a HIGH PEEP alarm will sound.

The airway pressure waveform displayed in the LCD is an accurate representation of proximal airway pressure. Large expiratory pressure changes that occur with a short period of time create temporary pressure gradients between the patient's lungs and the proximal airway pressure sensor. Unless PEEP is used, this condition is not apparent because equalization of positive pressure does not occur with a "zero" baseline. Compliance and resistance effect exhalation time. Patients with higher airway pressure resistance will momentarily alter the exhalation waveform appearance by causing a greater pressure differential between the lungs and ventilator circuit. The Ventilator's PEEP circuitry and software attempt to learn the patient's expiratory characteristic. Learning is an ongoing process and fine adjustments can be made to each breath as required. By doing so, pressure "undershoot" caused by gradient differences is minimized, or eliminated altogether. The initial learning process typically takes from 1 to 6 breaths. During this process, a temporary PEEP "baseline" is established for each breath so that triggering sensitivity is not decreased.

The display area for PEEP is on the top line, immediately below its respective pushbutton switch. The PEEP OFF/ON-SET display will blank when a SYSTEM FAILURE Alarm occurs.

8.8.6 Pressure Plateau (PLATEAU)

When the ventilator is turned ON, PLATEAU is OFF (its default value). It becomes operable, only in the ACV and SIMV operating modes, by pressing the PRESSURE PLATEAU OFF/ON Pushbutton Switch. The PLATEAU value is automatically referenced 10 cmH_2O below the HIGH PRESSURE ALARM/PEAK INSPIRATORY PRESSURE RELIEF Control setpoint. PRESSURE PLATEAU has an absolute range of 5 to 90 cmH_2O.

When a PLATEAU value is reached, gas flow is alternately cycled OFF and ON, to maintain the PLATEAU, until the inspiratory cycle is completed. If inspiratory pressure attempts to rise above the HIGH PRESSURE ALARM/PEAK INSPIRATORY PRESSURE RELIEF Control setting, Ventilator will open the exhalation valve until pressure falls to the PLATEAU level. If the Ventilator detects a leak in its disposable patient circuit, or any of its connections, additional gas flow is allowed to maintain the PLATEAU.

The display area for PRESSURE PLATEAU is on the top line, immediately below its respective pushbutton switch. The PRESSURE PLATEAU display will blank when a SYSTEM FAILURE Alarm occurs.

8.9 Back-up Ventilator

The Ventilator contains a backup ventilator that is designed to provide a limited degree of operation should a CPU failure occur. A CPU failure is a hardware-detected computer failure that will trigger a SYSTEM FAILURE Alarm. Normal operation will stop, the LCD will blank, the ALARM LED illuminates (flashing), the system failure led illuminates (non-flashing) and a pulsing tone is heard. A SYSTEM FAILURE THAT is caused by a CPU failure will illuminate the SYSTEM FAILURE LED because the causing condition cannot assure safe operation of the primary ventilator. In such cases, a separate ventilator circuit embedded within the Ventilator begins automatic operation.

Its operating characteristics are as follows:

Rate	12 Breaths Per Minute
I:E Ratio	1:2 (1.67-seconds x 3.33- seconds)
Flow Rate	30 Liters Per Minute for duration of Inspiratory Time or until Peak Inspiratory Pressure threshold is reached
Peak Inspiratory Pressure Relief	40 cmH_2O
Gas Source prioritization	External Air, if available; or Internal Compressor, if operable; or External Oxygen, if available.
Audible System Failure Alarm Mute/Cancel	Pressing ALARM MUTE/CANCEL pushbutton switch cancels audible alarm.
Manual Trigger Override	Yes, followed by a 6-second reset period before automatic ventilation resumes.

NOTE
A SYSTEM FAILURE that is caused by patient circuit pressure exceeding 40 cmH_2O for 5-seconds, continuously, will not cause the BACKUP VENTILATOR to activate. Instead, the ALARM LED illuminates (flashing), the SYSTEM FAILURE LED illuminates (non-flashing), a non-mutable continuous tone is heard, and the patient circuit exhalation valve is latched open-to-atmosphere.

8.10 Ventilator Diagnostics

The ventilator contains numerous alarm circuits, designed to alert attendant personnel and protect the patient. Alarm messages appear in a dedicated area on the LCD display. This area is called the ALARM MESSAGE CENTER (AMC).

The AMC is the centralized location for alarm information. It consists of a 4-line display area. Each alarm may be displayed with a short, accompanying message (two lines maximum); or simply as an alarm announcement that consists only of the alarm name. The number of simultaneous alarms determines how alarm function information is displayed.

The AMC will display one alarm with accompanying message; or two simultaneously occurring alarms with respective messages. The first occurring alarm (name and message), occupies AMC's top two lines. If a second alarm occurs while the first alarm is still unresolved, its name and message occupies the AMC's third and fourth lines. If three or more alarms become active simultaneously, the AMC reverts to showing each alarm by name only. There are no accompanying messages. When more than four alarms occur simultaneously, the words "LOW/FAIL" are blanked from the O_2 and EXT AIR alarm names.

When there are two alarms with messages displayed in the AMC and one becomes resolved, the remaining alarm with message will occupy lines one and two.

When three alarm names are displayed in the AMC and one alarm becomes resolved, the AMC reverts to displaying the two remaining alarms with their respective messages.

Normally, each and every alarm is displayed on the LCD. However, a CPU problem will trigger a SYSTEM FAILURE that causes normal operation to stop and the LCD to blank. A SYSTEM FAILURE LED illuminates whenever a SYSTEM FAILURE alarm condition occurs. It is accompanied by continuous, non-mutable tone. The SYSTEM FAILURE LED illuminates because the ALARM LED and LCD are rendered inoperable by the SYSTEM FAILURE. The ALARM Indicator led illuminates whenever an alarm causing condition, other than SYSTEM FAILURE occurs. It provides a supplemental alert when operating in a high noise environment or from a distance that might make LCD readability difficult. A pulsing audible signal accompanies each alarm.

Alarm conditions, depending upon type, may be temporarily muted or canceled. Alarms are categorized as OPERATING, NON-OPERATING, or ADVISORY. An **Operating** Alarm may be muted successively and allows continued operation. Mutable alarms will reset automatically when the alarm condition is no longer valid. **Non-Operating** Alarms cannot be muted and do not allow operation to begin/continue. **Advisory** alarms permit continued operation and can be muted once. AMC display of Advisory Alarms blank if a non-operating alarm occurs or, more than four Operating Alarms are simultaneously active. Table 8-7 classifies the types of alarms and other diagnostics for the ventilator.

Table 8-7. Ventilator Diagnostics

Alarm/Indication	Condition	Corrective Action
GENERAL		
LSTAT on, Ventilator will not power up	Ventilator not receiving power. Internal failure	Shut down LSTAT then power up and turn on Ventilator. If indication persists contact IMS support.
Ventilator on, No air	Internal or external air may not be connected. Internal failure	Check internal and external air connections. Reconnect if necessary. If indication persists, contact IMS support.
Ventilator starts then stops	Internal Failure	Contact IMS support.
Ventilator functioning, but performance not optimum.	Possible clogged or dirty inlet filters.	Check Inlet filters. Clean or replace as necessary. If situation persists, contact IMS support.

Alarm/Indication	Condition	Corrective Action
OPERATING ALARMS		
LOW PRESSURE	Initiates when PIP fails to exceed the LOW PRESSURE ALARM setpoint for two consecutive breaths and causes its LCD setpoint indicator, and DIGITAL BAR GRAPH setpoint indicator, to blink. AMC will display: LOW PRESSURE-PEAK INSPIRATORY PRESSURE TOO LOW or LOW PRESSURE. The AMC will blank if a non-operating alarm occurs. The LOW AIRWAY PRESSURE Alarm setpoint indicator adjacent to the DIGITAL BAR GRAPH will alternately blink, with the HIGH PRESSURE Alarm Control LCD setpoint indicator, during a PRESSURE ALARM SETTINGS Alarm.	1. Confirm settings. 2. Check for patient circuit leaks. 3. Check patient. 4. It situation persists contact IMS support.
DISCONNECT	Initiates when a disconnect is sensed in the patient circuit. When activate the AMC displays: DISCONNECT-CHECK CIRCUIT CONNECTIONS or DISCONNECT. The AMC will blank if a non-operating alarm occurs If a DISCONNECT Alarm occurs during a LOW PRESSURE Alarm, both alarm messages will appear in the AMC. If a DISCONNECT Alarm occurs first, the LOW PRESSURE Alarm is disabled. DISCONNECT Alarm is armed in all operating modes, however, its activating conditions are different. ASSIST-CONTROL & SIMV modes - The microprocessor looks for a positive pressure rise of at least 3 cmH_20 to occur within 75% of the INSPIRATION TIME Control setting (applies only to ventilator-generator breaths). If a positive pressure rise does not occur within this period, the DISCONNECT Alarm activates. The microprocessor alarm circuit activates when respiration's (spontaneous and/or Ventilator generated) are undetected for a period that is equal to 19 seconds minus INSPIRATORY TIME (range = 16.0 to 18.9 seconds); or CPAP mode-when no spontaneous breathing is detected for 10 seconds (based on a 30 second moving average). To qualify the alarm condition as DISCONNECT, or APNEA, the microprocessor delivers controlled ventilation at the INSPIRATION TIME setting. If a pressure rise of at least 3 cmH_2O occurs within 75% of the INSPIRATION TIME Control setting (1 second when in CPAP mode). The APNEA Alarm is activated. If a pressure rise is not detected, the Ventilator returns to its respective mode and activates its DISCONNECT alarm. If no change in status occurs, the controlled ventilation test is repeated every 30 seconds.	Check for disconnect and reconnect as necessary.

Alarm/Indication	Condition	Corrective Action
HIGH PRESSURE	Activates when the patient's airway pressure exceeds the HIGH AIRWAY PRESSURE ALARM Control setting for 2 seconds (continuous), or 250 milliseconds for four consecutive ventilations. The HIGH PRESSURE alarm setting is also the safety setting for Peak Inspiratory Pressure Relief. Excessive flows and/or inspiration times, occlusion of the patient circuit or a change in the patient's physiological condition can cause a rise in peak inspiratory pressure (PIP) the HIGH AIRWAY PRESSURE ALARM Control setting. When a high PIP condition occurs (exceeding the HIGH AIRWAY PRESSURE ALARM Control setting by 1 cmH_2O), the Ventilator causes the disposable ventilator circuit exhalation valve to open. This allows excess pressure to "dump" through the exhalation valve to atmosphere, while allowing the INSPIRATION TIME cycle to continue. When the patient circuit pressure falls below the trigger point (1 cmH_2O below the HIGH PRESSURE ALARM Control setting), the exhalation valve is closed and gas flow is allowed to resume for the remainder of the inspiratory cycle. The HIGH PRESSURE Alarm initiates when PIP exceeds the HIGH PRESSURE Alarm setpoint for 4 consecutive breaths, or 2 seconds continuously, and causes its LCD setpoint indicator, and DIGITAL BAR GRAPH setpoint indicator to blink. When activated the AMC displays: HIGH PRESSURE-PEAK INSPIRATORY PRESSURE TOO HIGH or HIGH PRESSURE. The AMC will blank if a non-operating alarm occurs. The HIGH AIRWAY PRESSURE Alarm setpoint indicator adjacent to the DIGITAL BAR GRAPH will alternately blink, with the LOW PRESSURE Alarm Control LCD setpoint indicator, during a PRESSURE ALARM SETTINGS Alarm.	1. Check Settings. 2. Check patient. 3. Check patient circuit for proper operation. 4. If situation persists, contact IMS support.
APNEA	Functions in the ACV, SIMV and CPAP modes. When activated in ACV or SIMV, the AMC displays APNEA-CHECK PATIENT FOR SPONTANEOUS BREATHING or APNEA. When activated in CPAP, the AMC displays APNEA-CPAP AVERAGE RATE LESS THA 6-BPM or APNEA. The AMC will blank if a non-operating alarm occurs APNEA ALARM DURING ACV OR SIMV OPERATION: The APNEA alarm activates when the period between positive and/or negative pressure deflections (spontaneous and/or the Ventilator generated respiration's) exceeds 19 seconds minus the INSPIRATION TIME setting. APNEA ALARM DURING CPAP OPERATION: The APNEA Alarm activates when no spontaneous breathing is detected for 10 seconds (based on a 30-second moving average).	1. Check patient for spontaneous breathing 2. Mute alarm.
HIGH PEEP	Initiates when the inspiratory cycle begins before end expiratory pressure plateaus. When activated the AMC displays: HIGH PEEP - INSPIRATION BEGAN BEFORE END PRESSURE PLATEAU or HIGH PEEP, and the PEEP OFF/ON-SET LCD display area will alternately flash. The AMC will blank if a non-operating alarm occurs.	This alarm is disabled when the peep off/on-set Pushbutton switch is set to "0"

Alarm/Indication	Condition	Corrective Action
O_2 LOW/FAIL	Initiates when a pressure less than 35 psi (± 2 psi) is sensed from an external oxygen supply. If gas mixing, or 100% oxygen, was chosen, the FIO_2 Alarm will also sound, and the CPU will terminate the oxygen source. **NOTE** When switching between gas sources, a V_T Alarm may occur on the first transition breath. This alarm will self-cancel on the second breath and is due to monitoring software adjustments that occur when a gas source change is invoked (manually or automatically). EXTERNAL AIR (if connected), or the internal compressor, will provide the tidal volume. The O_2 LOW/FAIL Alarm can be canceled by setting the AIR/OXYGEN MIXER setpoint to 21% or, restoring the oxygen source pressure to greater than 50 psi (±5 psi). When activated the AMC displays: O_2 LOW/FAIL-CHECK OXYGEN SOURCE CONNECTIONS, O_2 LOW/FAIL, or O_2. The AMC will blank if a non-operating alarm occurs.	Check connections
EXT AIR LOW/FAIL	Initiates when a pressure less than 35 psi (± 2 psi) is sensed from an external source or compressed air and causes the EXTERNAL AIR OFF/ON LCD indicator to blink. If the AIR/OXYGEN MIXER setpoint is greater than 21%, an FIO_2 Alarm is momentarily generated as additional oxygen flow is used to make up the air deficit contribution to tidal volume. The Ventilator's CPU terminates the EXTERNAL AIR source, and activates the internal compressor, canceling the FIO_2 Alarm. **NOTE** When switching between gas sources, a V_T Alarm may occur on the first transition breath. This alarm will self-cancel on the second breath and is due to monitoring software adjustments that occur when a gas source change is invoked (manually or automatically). The EXTERNAL AIR LOW/FAIL Alarm can be canceled by pressing the EXTERNAL AIR Pushbutton Switch to "OFF" which cancels the alarm or, restoring the EXTERNAL AIR source to a pressure to greater than 50 psi (± 5 psi). When activated the AMC displays: EXT AIR LOW/FAIL-CHECK AIR SOURCE/CONNECTIONS, EXT AIR LOW/FAIL or EXT AIR. The AMC will blank if a non-operating alarm occurs.	Check air source/connections.
FIO_2	Initiates when the oxygen component, or the air component, of the AIR/OXYGEN MIXER is unable to meet its proportion of the gas mixture. If the alarm is caused by an EXT AIR LOW/FAIL condition, the CPU terminates the EXTERNAL AIR source and activates its internal compressor, canceling the FIO_2 Alarm. **NOTE** When switching between gas sources, a V_T Alarm may occur on the first transition breath. This alarm will self-cancel on the second breath and is due to monitoring software adjustments that occur when a gas source change is invoked (manually or automatically). The EXTERNAL AIR LOW/FAIL Alarm remains, and the EXTERNAL AIR Pushbutton Switch LCD indicator continues blinking. The alarm is canceled when the EXTERNAL AIR Pushbutton Switch is pressed to "OFF". When activated the AMC displays: FIO2-GAS MIX ERROR. CHECK SOURCE SETTINGS CONNECTIONS or FIO_2. The AMC will blank if a non-operating alarm occurs.	Check source settings/connections

Alarm/Indication	Condition	Corrective Action
PRESSURE ALARM SETTINGS	Initiates when the HIGH PRESSURE ALARM and LOW PRESSURE ALARM setpoints are reversed (i.e., low setpoint is set higher than their high setpoint). Both Control setpoint indicators, and both indicators adjacent to the DIGITAL BAR GRAPH, alternately blink during a PRESSURE ALARM SETTINGS Alarm. When activated the AMC displays: PRESSURE ALARM SETTINGS-ALARM SETTINGS REVERSED or PRESSURE ALARM SETTINGS. The AMC will blank if a non-operating alarm occurs.	Recheck setting for reversed HI-Low settings.
V_T	**NOTE** When switching between gas sources, a V_T Alarm may occur on the first transition breath. This alarm will self-cancel on the second breath and is due to monitoring software adjustments that occur when a gas source change is invoked (manually or automatically). Initiates when delivered tidal volume is not within 10% of set tidal volume. Its usable range is from 100 to 3000ml. When activated, the TIDAL VOLUME display will alternately flash the "####set" and '####del" volumes; the AMC displays: V_T - DELIVERED TIDAL VOLUME DOES NOT EQUAL SET TIDAL VOLUME or V_T. The AMC will blank in the CPAP mode, or if a non-operating alarm occurs. A momentary V_T Alarm may occur when adjustments to control settings cause a large change in V_T. This alarm will self-cancel on the second breath as monitoring software makes adjustments.	1. Confirm settings. 2. Adjust settings to compensate for alarm.
COMP	Initiates when the compressor output exceeds ± 30% of its intended contribution to tidal volume for 3 consecutive breaths (the compressor alarm monitoring range requires a total tidal volume of at least 200ml {sum of all gases if FIO_2 is greater than 21%} with the compressor delivering a flow rate of at least 10 LPM). If the alarm occurs during the operation with external oxygen, the Ventilator's CPU instructs the oxygen source to make up for any tidal volume deficit caused by the compressor. When this occurs, an FIO_2 alarm is generated. If EXTERNAL AIR is connected but not in use, the Ventilator's CPU instructs the EXTERNAL AIR source to take over for the internal compressor (pressing the MUTE/CANCEL Pushbutton Switch cancels the COMP Alarm). If the alarm occurs and no external air or oxygen source is connected, a TIDAL VOLUME Alarm is generated, and the TIDAL VOLUME display will alternately flash the '####set" and "####del" volumes. This will last momentarily because a VENTILATOR FAIL Alarm (CODE 2 or CODE 3), will cause operation to crease. The AMC displays: COMP - COMPRESSOR OUTPUT LOW/FAIL or COMP. The AMC will blank if a non-operating alarm occurs.	1. Hook up to external air to bypass problem or, 2. Switch to 100% oxygen. 3. If situation persists, contact IMS support.
NON-OPERATING ALARMS		
Inverse I:E	Occurs when the inspiration time Control is set for a period that is longer than the exhalation period. When this alarm occurs, an audible tone is heard, the Ventilator's CPU will cause the disposable ventilator circuit exhalation valve to open to atmosphere (antiasphyxia condition), the INSPIRATION TIME/I:E RATIO Display will blink and the AMC displays: INVERSE I:E-INSPIRATORY TIME LONGER THAN EXHALATION TIME or INVERSE I:E. The AMC will blank in the CPAP mode, or if a SYSTEM FAILURE Alarm occurs. Apnea monitoring is disabled during and inverse I:E Alarm.	Lower the RATE Control setting for lower the INSPIRATION TIME Control setting (or both).

Alarm/Indication	Condition	Corrective Action
Transducer Calibration	Activates when the pressure transducer "zero" baseline exceeds ± 1 cmH$_2$0. When activated, an audible tone is heard and the AMC displays: TRANSDUCER CALIBRATION - CALIBRATE TRANSDUCER or TRANSDUCER CALIBRATION. The AMC will blank if a SYSTEM FAILURE Alarm occurs. The TRANSDUCER CALIBRATION Alarm resets itself after recalibration is completed.	Recalibrate.
Transducer Calibration Abort	Activates when the TRANSDUCER CALIBRATION procedure is stopped prematurely. When activated, an audible tone is heard and the AMC displays: TRANSDUCER CALIBRATION ABORT-RECALIBRATE TRANSDUCER or TRANSDUCER CALIBRATION ABORT. The AMC will blank if a SYSTEM FAILURE Alarm occurs. The TRANSDUCER CALIBRATION ABORT Alarm will reset itself when recalibration is performed	Recalibrate.
System Failure	Activates when the Ventilator's CPU is forced to shutdown normal operation or a CPU failure has occurred. This alarm is usually related to a hardware problem. It will cause the LCD to blank, and the SYSTEM FAILURE LED to illuminate.	1. Restart 2. If situation persists, contact IMS support.
Ventilator Fail	Initiates when any one of seven ventilator failure-causing conditions occurs as described below. These conditions will not cause the LCD to blank and some may be operator correctable. Messages will appear in the AMC. A VENTILATOR FAIL Alarm will not cause the SYSTEM FAIL LED to illuminate.	
1. Self-Test Failure	Ventilator fails to successfully complete self-check, The AMC will display: TRANSDUCER CALIBRATION-CALIBRATE TRANSDUCER VENTILATOR FAILURE DETECTED FAILURE CODE 1 SELF CHECK FAILURE -OR- If SELF-CHECK Alarm is not related to the Transducer /calibration: VENTILATOR FAILURE DETECTED FAILURE CODE 1 SELF-CHECK FAILURE!	1. Restart in CAL mode. 2. Attempt to re-initiate ventilation. 3. If situation persists, contact IMS support.
2. No Gas and Compressor Failure	Internal compressor has failed and no external gas is available. The AMC will display: VENTILATOR FAILURE DETECTED Failure CODE 2 NO GAS AND COMPRESSOR FAILURE!	1. Restart 2. Hook up external gas source 3. If situation persists, contact IMS support.
3. Total Flow Backup Check	Occurs when the sum of the flows (O$_2$, air and internal compressor) exceeds set flows by ± 50% for 5 consecutive breaths. There must be a total flow rate of at least 10 LPM and a total tidal volume of at least 200ml for this alarm to operate. The AMC will display: VENTILATOR FAILURE DETECTED FAILURE CODE 3 TOTAL FLOW BACKUP CHECK FAILURE!	1. Check inlets and filters. 2. Restart. 3. If situation persists, contact IMS support.
4. Excessive Airway Pressure	Occurs when a continuous pressure, above 100 cmH$_2$O, is sensed in the patient circuit for more than 2 seconds. The AMC will display: VENTILATOR FAILURE DETECTED FAILURE CODE 4 EXCESSIVE AIRWAY PRESSURE!	Turn off the Ventilator, then restart to clear a SYSTEM FAILURE Alarm caused by high pressure.

Alarm/Indication	Condition	Corrective Action
5. Memory Check Failure	Occurs when the MEMORY CHECK portion of self-check fails. The AMC will display: VENTILATOR FAILURE DETECTED FAILURE CODE 5 MEMORY CHECK FAILURE!	1. Restart. 2. If situation persists, contact IMS support.
6. Exhalation Valve Failure	Occurs when a failure of the exhalation backup solenoid is sensed. The AMC will display: VENTILATOR FAILURE DETECTED FAILURE CODE 6 EXHALATION VALAVE FAILURE! Possible Vent Drain Hole clog.	1. Check Exhalation Valve for leaks or cracks and replace as necessary 2.If situation persists, check the Vent Drain hole in the foot end of the stretcher foot well on the patient's left side. Stretcher will have to be raised to access the hole. Clear any obstructions. 3. If situation still not rectified, then contact IMS support.
7. Excessive Negative Pressure	Occurs when a continuous negative pressure exceeding -10 cmH_2O for 1.5 seconds is sensed. The AMC will display: VENTILATOR FAILURE DETECTED FAILURE CODE 7 EXCESSIVE NEGATIVE PRESSURE!	1. Restart. 2. If situation persists, contact IMS support.
ADVISORY ALARMS		
Inspiration Time Truncated to 3-sec	Initiates when control settings would cause an inspiration time to exceed 3 seconds. It is disables in CPAP mode. When activated, operation is allowed to continue, an audible tone is heard and the AMC displays: INSPIRATION TIME TRUNCATED TO 3-SEC-NOTE I-TIME & I:E or INSPIRATION TIME TRUNCATED. The AMC will blank if a non-operating alarm occurs. A sigh breath that would exceed 3.0 seconds is truncated but will not activate this alarm.	Pressing the ALARM MUTE/CANCEL push button Switch cancels this alarm's audible component only, and the AMC message remains.
Plateau Volume	Initiates when delivered pressure plateau tidal volume is less than set tidal volume by more than 5%. When activated, operation is allowed to continue, an audible tone is heard and the AMC displays: PLATEAU VOLUME-DELIVERED VOLUME LESS THAN SET VOLUME or PLATEAU VOLUME. The TIDAL VOLUME LCD Display will flash "####set" volume (delivered volume is not displayed), and V_{min} is blanked (ACV mode). The AMC will blank in the CPAP mode, or if a non-operating alarm occurs.	Pressing the alarm mute/cancel Pushbutton Switch cancels this alarm's audible component only, the AMC message and alternating display remain. This alarm replaces the V_t Alarm during pressure plateau operation. It is disabled when CPAP operation is selected.
V_T settings	Initiates whenever the sum of the flows of the selected gases would exceed a flow rate of 60 liters per minute (LPM). When activated, the AMC displays: V_T SETTINGS - I-TIME X FLOW UNABLE TO DELIVER SET VOLUME or V_T SETTINGS. The TIDAL VOLUME LCD Display will alternately flash "####set" and "####del". The AMC will blank in the CPAP mode, or if a non-operating alarm occurs.	Pressing the alarm mute/cancel Pushbutton Switch cancels this alarm's audible component only, the AMC message and alternating display remain.

Alarm/Indication	Condition	Corrective Action
Preventative Maintenance	Initiates after 2000 hours of cumulative use, or 12 months, whichever occurs first. Preventative maintenance will insure that this device has been cleaned, tested, calibrated, and serviced to manufacturer's specifications. When activated the AMC displays: PREVENTATIVE MAINTENANCE DUE - CONTACT CUSTOMER SERVICE or PREVENTATIVE MAINTENANCE DUE. The AMC will blank if a non-operating alarm occurs.	Perform Preventative Maintenance. See Section 12.5.6 for details.
Extended Non-Use Storage	Initiates at power-up after 6 months of continuous non-use/storage has occurred. When activated the AMC displays: EXTENDED NON-USE/STORAGE - TEST BEFORE PATIENT USE or EXTENDED NON-USE/STORAGE. The AMC will blank if a non-operating alarm occurs.	Unit must be examined following 6 months continuous storage/non-use. Ensure the LSTAT batteries are recharged and run a complete operation test before attempting patient use. Servicing may be required. See section 5 for servicing details. Servicing should be performed by qualified personnel only.
(None) Manual Flow Zero does not clear offset.	FLOW ZERO button may be inoperative.	1. Attempt manual FLOW ZERO again. If offset not cleared, remove and replace Flow Sensor. 2. If situation persists, contact IMS support.

CHAPTER 9 OXYGEN

9.1 Intended Use and Limitations

This chapter describes oxygen use when not using the ventilator. Use of oxygen in conjunction with the Ventilator is described in CHAPTER 8.

WARNING: When the trickle charger is in use, it is recommended that the oxygen bottle valve be turned off.

WARNING: The circuit breakers must be opened before the removal of the internal oxygen bottle because exposed wiring poses a potential shock hazard.

WARNING: Turn off oxygen bottle if stored for short periods (1 week or longer).

9.2 Equipment

9.2.1 Flowmeter

On the Outboard side of the head fairing there is a connector for an Oxygen Bypass Flowmeter. The flowmeter is used to administer 100% oxygen and bypass the ventilator.

The Flowmeter comes pre-assembled with a Quick Disconnect fitting, anti-rotation tube and a swivel connector (Figure 9-3). Figure 9-1 illustrates the O_2 bypass fitting.

The Flowmeter operates when plugged into the O_2 bypass fitting and the Oxygen Switch is turned on. The flow of oxygen can be controlled by a flow meter at the O_2 bypass.

To terminate use of the Flowmeter, turn it off and unplug it from the head fairing.

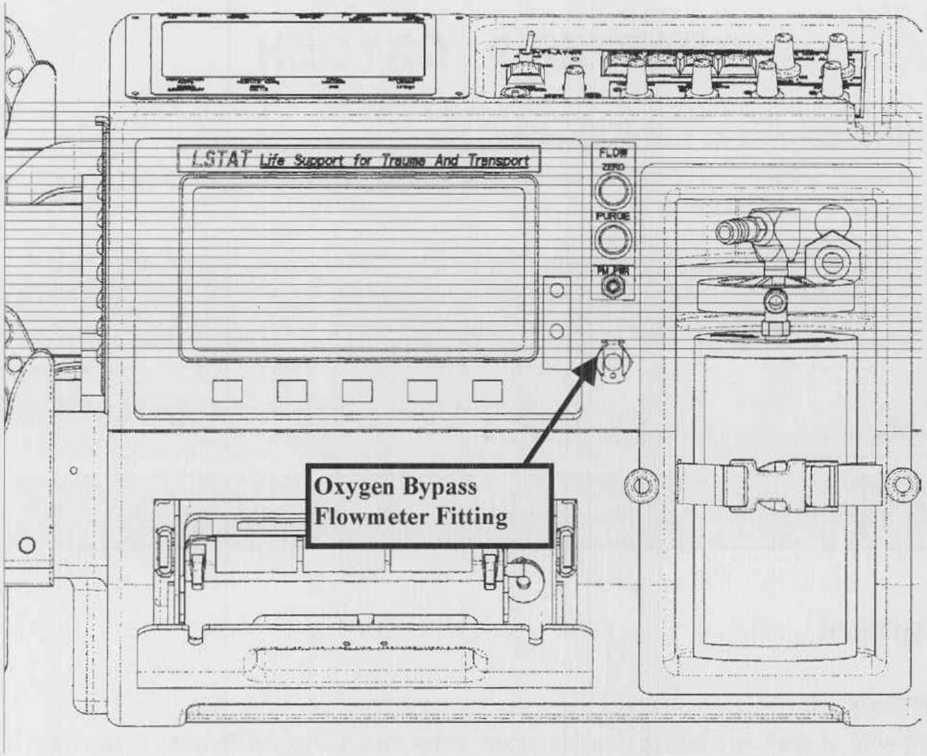

LSTAT Life Support for Trauma And Transport
FLOW
ZERO
PURGE
Oxygen Bypass
Flowmeter Fitting

Figure 9-1. Oxygen Bypass Flowmeter

9.3 Accessories

Use the accessories listed in Appendix D and where called in this section.

9.4 Controls and Displays

9.4.1 Oxygen Switch

Oxygen flow is controlled by the Oxygen On/Off/Chk switch located on the head fairing (Figure 9-2).

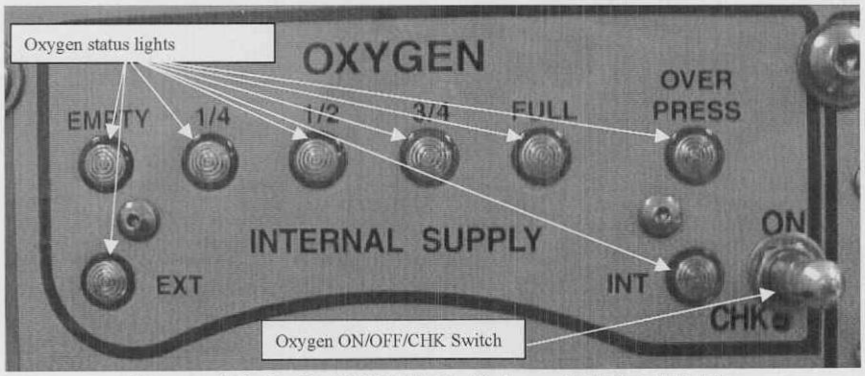

Oxygen status lights
OXYGEN
EMPTY
1/4
1/2
3/4
FULL
OVER
PRESS
INTERNAL SUPPLY
EXT
INT
ON
CHK
Oxygen ON/OFF/CHK Switch

Figure 9-2. O_2 On/Off/Chk Switch and Status Lights

9.4.2 Oxygen Status Indicator

Figure 9-2 shows the Oxygen status indicator panel. Table 9-1 identifies the lights.

Table 9-1. Oxygen Indicator Lights

Label	Light	Status
EXT	Steady Green	External O_2 system pressurized; onboard supply bypassed.
EMPTY	Flashing Red	Less than 510 psi (less than 1/8).
1/4	Steady Yellow	Less than 1230 psi, greater the 510 psi. (Less than 3/8; greater the 1/8).
1/2	Steady Green	Less than 1950 psi, greater than 1230 psi (Less than 5/8; greater than 3/8).
3/4	Steady Green	Less than 2650 psi, greater than 1950 psi (Less than 7/8; greater than 5/8).
FULL	Steady Green	Less than 3300 psi, greater than 2651 psi (Less than 3300 psi; greater than 7/8).
OVER PRESS	Flashing Red	O_2 system exceeds 3300 PSI (110%). Turn off oxygen subsystem and remove and replace O_2 bottle.
INT	Steady Yellow	O_2 system pressurized.

NOTE

3000 psi yields approximately 1 hr. of use at 8 liters per minute

9.4.3 Oxygen Bottle Pressure Gauge

The oxygen pressure gauge is visible from the foot panel when the patient pad is removed.

9.5 Internal Oxygen

NOTE

If internal oxygen supply is to be used and external oxygen is connected, the pressure on the external supply port must be relieved by removing the supply hose to expose the supply port to ambient pressure.

NOTE

When using internal oxygen, the internal/external oxygen lights may briefly change to external. When oxygen is NOT flowing the lamp may remain on until flow begins.

WARNING: To ensure a continuous flow of oxygen, make sure the oxygen flow meter is set directly on a number. Failure to do so may result in a loss of oxygen delivery.

1. Toggle *SYSTEM POWER* to ON.
2. Connect the Flowmeter to the oxygen bypass fitting (Figure 9-1).
3. Connect the O_2 tube attached to the O_2 mask to one of the oxygen bypass valves (Figure 9-3).
4. Attach the O_2 mask to the patient.

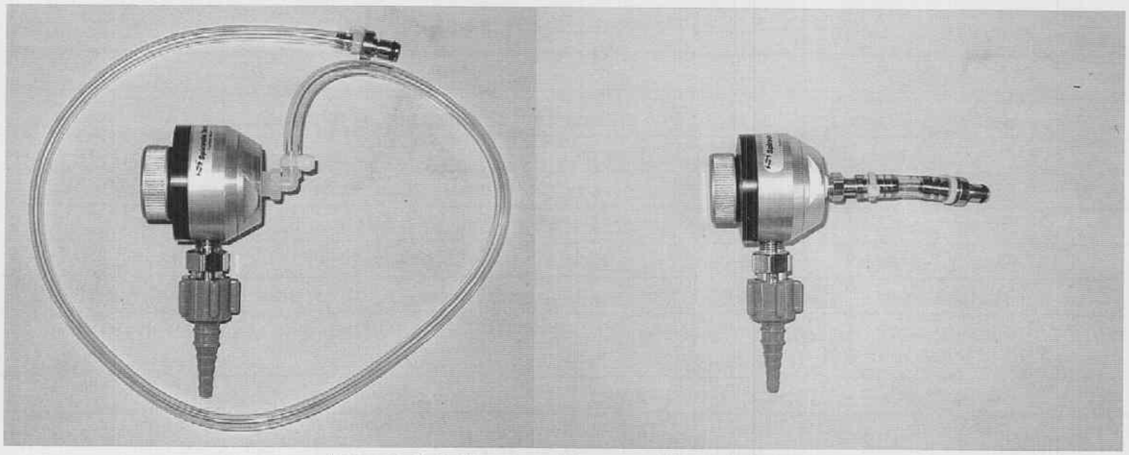


Figure 9-3. Oxygen Bypass Connectors

5. Place the Oxygen Switch to the ON position.
6. Check the OXYGEN INTERNAL SUPPLY (Figure 9-2) to verify internal bottle capacity.
7. Lift up the patient footpad to expose the oxygen bottle window.
8. View the mechanical gauge on the bottle assembly
9. Observe oxygen pressure is sufficient.
10. Monitor the oxygen internal supply status during use.
11. Turn Oxygen Switch to the OFF position to stop the flow of internal oxygen
12. Disconnect O_2 mask and tube from patient.
13. Disconnect Flowmeter from LSTAT.

9.6 External Oxygen

CAUTION

When the EMPTY lamp (flashing red) is lit, then a caution condition of imminent (less than 250 psi usable O2 which is less than 5 minutes at 8 lpm) exhaustion of the onboard oxygen supply is indicated.

NOTE

Use of external oxygen is always preferred when available. This helps preserve the onboard oxygen supply when external oxygen is not available.

CAUTION

If OVER PRESS Indicator is illuminated or the Oxygen bottle mechanical pressure gauge reads greater than 3300 psi, or if level is insufficient for patient need, remove and replace the Oxygen bottle.

1. Toggle *SYSTEM POWER* to *ON*.
2. Connect either end of the green oxygen hose to the external oxygen source.
3. Remove the protective cap from the fitting labeled External Oxygen (Figure 9-4).
4. Connect the external oxygen supply hose to the external oxygen fitting.

CAUTION

When external oxygen is in use, it is recommended that the Onboard Oxygen System also be turned on to provide an uninterrupted supply of oxygen in the event of an external source disconnect or a loss of external oxygen pressure.

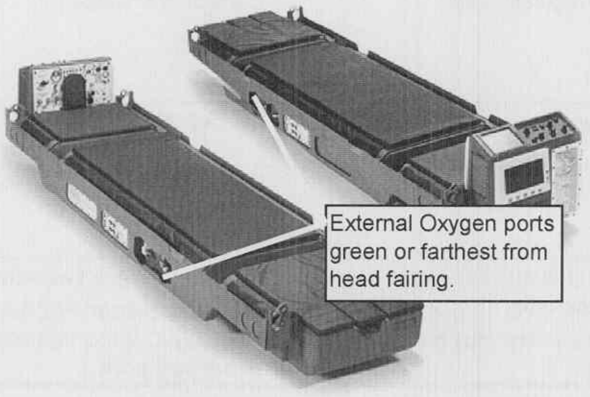


Figure 9-4. External Oxygen Ports

5. Connect the Flowmeter to the O_2 bypass fitting (Figure 9-1).
6. Connect the O_2 tube attached to the O_2 mask to the swivel (Figure 9-3).
7. Attach the O_2 mask to the patient.
8. Open the shut off valve on the external supply to begin oxygen flow.
9. Observe EXT on Oxygen Indicator Panel is lit.
10. Place the Oxygen Switch to the ON position.
11. Close the external oxygen shut-off mechanism to stop external oxygen flow.
12. Disconnect the external oxygen supply hose from the external oxygen port.
13. Place Oxygen Switch to the OFF position to stop the flow of internal oxygen (Figure 9-2).
14. Disconnect O_2 mask and tube from patient.
15. Disconnect Flowmeter from LSTAT.

9.7 Oxygen Diagnostics

Table 9-2 is a listing of diagnostics for the Oxygen subsystem.

Table 9-2. Oxygen Diagnostics

Indication	Condition	Corrective Action
EMPTY LED lit	Oxygen bottle is empty	Remove empty bottle and replace with full bottle.
External O_2 hooked up and on but no O_2 flow	External O_2 valve or regulator is not turned on and/or, Faulty internal/external source selecting valve.	1. Turn on external O_2. 2. Contact IMS support
O_2 bottle shows 3,000 psi, but no O_2 delivered	O_2 switch is in the OFF position. Failed gauge. Pressure or flow regulation circuit failure	1. Open Oxygen switch to the ON position 2. Shut-Off Assembly/ Replace Bottle 3. Contact IMS support.
O_2 runs out before 60 minutes elapse	O_2 bottle was undercharged. Flow settings exceed 8 liters/min.	1. Check bottles for correct charging pressures 2. Check and/or replace improperly set flow-regulating device.
External O_2 on, LED on, but no external O_2	Insufficient pressure or bad LED/pressure switch.	Check pressure. If situation still persists contact IMS support.

Indication	Condition	Corrective Action
O_2 gauge registers an excess of 3300 psi	O_2 bottle overcharged	Place Oxygen Switch to the OFF position and Remove and Replace O_2 bottle.
O_2 OVERPRESS LED lit	Oxygen bottle is overfilled	Place Oxygen Switch to the OFF position Remove and Replace O_2 bottle.
External O_2 hook up and on, indicator lights show O_2 bottle pressure dropping	Faulty regulator seal.	Contact IMS support.
Oxygen on but LED's not lit.	LED failure	Contact IMS support.
O_2 bottle gauge does not indicate pressure, but there is O_2.	Failed gauge	Replace Bottle/Shut-Off Assembly
LSTAT power on, no O_2 LED's show O_2 pressure levels	Failed Operator interface board or LED assembly Oxygen Switch may be in the OFF position.	1. Place Oxygen switch to the ON position. 2. If situation persists, oxygen must be monitored manually. Contact IMS support at earliest convenient point.

9.8 Oxygen Bottle Removal and Replacement

See section 12.5.7 for removal and replacement instructions.

CHAPTER 10 CLINICAL ANALYSIS

10.1 Intended Use and Limitations

The Portable Clinical Analyzer is used for the in vitro qualification of various blood factors. The specific tests and intended uses are summarized in Table 10-1.

Do not operate at temperatures below 16°C or above 30°C.

Do not operate in flight.

10.2 Equipment

The Portable Clinical Analyzer is a "stand alone" system operated by two 9v lithium batteries and is located in the foot compartment (Figure 10-3). Figure 10-1 shows the Portable Clinical Analyzer and a test cartridge.

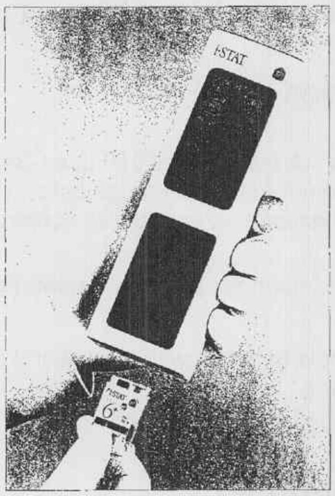


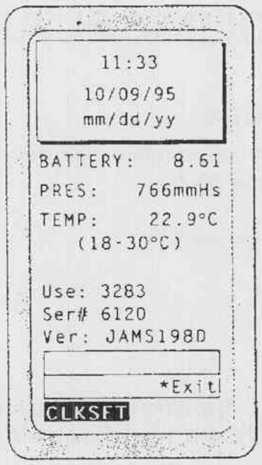
Figure 10-1. Portable Clinical Analyzer

10.3 Accessories

Utilize the accessories listed in Appendix D and where called out in this section.

10.4 Changing Date and Time

1. Press the **Menu** softkey and select Status.
2. Press the CLKSET softkey to convert the softkeys into arrows.
3. Using the arrow keys, move the cursor under the digit to be changed.
4. Use the keypad to change the digit. Clock is entered in 24-hour format.
5. When all changes are made, press the ENT key to store the changes. The analyzer will not store inappropriate entries. Figure 10-2 shows date and time on the Portable Clinical Analyzer.



```
      11:33
    10/09/95
    mm/dd/yy
BATTERY:    8.61
PRES:    766mmHs
TEMP:     22.9°C
   (18-30°C)

Use: 3283
Ser# 6120
Ver: JAMS198D

           *Exit
CLKSET
```

Figure 10-2. Changing Date and Time

10.5 Replacing the Batteries

Two 9-volt batteries power the analyzer. A minimum of 250 uses can be expected before replacement; overall uses for a set of batteries are dependent on cartridge type. The analyzer will indicate when battery replacement is needed with a message on the display screen.

1. Place the analyzer upside down and open the battery compartment door.
2. Remove the old batteries.
3. Orient the (+) and (-) poles of the new batteries with the (+) and (-) labels in the battery compartment and slide the new batteries into place.
4. Close the battery door. The analyzer is ready for use.

10.6 Clinical Analyzer Operation

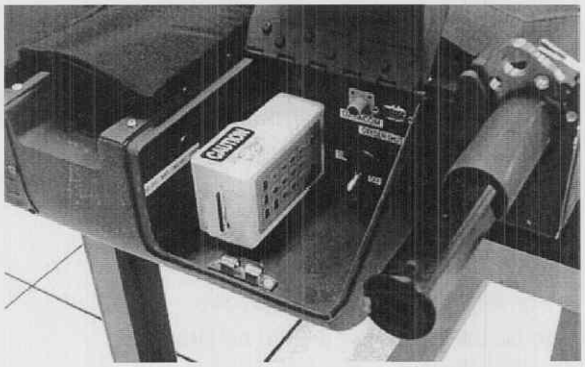


Figure 10-3. Portable Clinical Analyzer within the LSTAT

10.6.1 Electronic Simulator

Perform an electronic check on the analyzer using the External Electronic Simulator as needed for regulatory compliance.

1. Remove the Portable Clinical Analyzer (PCA) from the IR cradle in the LSTAT foot compartment (Figure 10-3).
2. Insert the Electronic Simulator into the slot in the base of the PCA. This is the same slot utilized for the insertion of the analysis cartridges. Do not touch the contact pads.

The PCA will then display the message: "CONTACTING CARTRIDGE".

The PCA will then display a prompt for an operator ID. This ID is included in the simulator record in the PCA and is up loaded on demand to the LSTAT.

A completion bar will be displayed showing a range from 0 to 120 seconds indicating that the test will take 120 seconds to complete. If a "LCK" message appears during this time, then the PCA battery is too weak to proceed with the test. Additionally, the following message will be displayed: "DO NOT REMOVE CARTRIDGE, ANALYZER NOT RESET, REPLACE BATTERIES". Replace the batteries leaving the simulator in the PCA and allow the test to continue. If the PCA displays the message: "ANALYZER INTERRUPTED, USE ANOTHER CARTRIDGE", then remove and replace the Electronic Simulator.

A "PLEASE WAIT" message will be displayed followed by "ELECTRONIC SIMULATOR". The completion bar will be displayed with "0" on the left and "120" on the right accompanied by the message "TIME TO RESULTS".

> **NOTE**
> A whining noise may be heard (in a quiet environment) from the PCA at this time. This is normal, as it is the sound of the internal motor being activated for the test.

At the conclusion of the test the following messages should be displayed:

"ELECTRONIC SIMULATOR"
"PASS"
"READY FOR USE"

If the test fails, then an error message will be displayed and further action may be required. This may include running a cartridge and re-running the simulator, updating the software or returning the PCA for repairs. See Section 4 for additional diagnostic information.

10.6.2 Test Cartridge

1. Take a blood sample observing the following precautions.

Blood Collection Precautions:

- Allow alcohol to dry over puncture site before collecting blood.
- Do not "milk" finger or heel while collecting blood.
- Do not draw above an I.V.
- Do not leave tourniquet on for more than 1 minute before collection.
- Samples for ACT testing should be collected into plastic devices (no glass) using no anticoagulant. For other tests, use only lithium or sodium heparin anticoagulants or collect using no anticoagulant. For ionized calcium, fill tubes to capacity, use capillary tubes or syringes with balanced heparin; or use no anticoagulant.
- Mix blood collected in tubes with anticoagulant by gentle inversion. Mix blood and anticoagulant by rolling syringe between the palms for at least 5 seconds. Then invert the syringe repeatedly for at least 5 seconds.
- Maintain anaerobic conditions (do not expose to air) when measuring pH, PCO_2, PO_2 and ionized calcium.

Handling the blood sample:

- Volume to fill cartridge is approximately 2 to 3 drops.

- Only fresh whole blood samples should be tested.
- Samples for ACT testing should be analyzed immediately after collection. Samples collected for lactate testing, or those without anticoagulant or in capillary tubes should be tested within 3 minutes.
- Samples for other tests, collected with anticoagulant, should be tested within 10 minutes. If the cartridge is not filled immediately after drawing and mixing the blood, the tube must be re-mixed thoroughly. Mix tubes by gentle inversion 7 times. Mix syringes by rolling between the palms for at least 5 seconds. Then invert the syringe repeatedly for at least 5 seconds. Discard 1-2 drops of blood.
- Test samples before icing.

2. Obtain a cartridge for testing observing the following precautions:
    - Handle the cartridge by its edges (Figure 10-4). Avoid touching the contact pads or exerting pressure over the center of the cartridge.
    - Store cartridges at 2 to 8^0 C. Do not use after expiration date.
    - Do not allow cartridges to freeze.
    - Allow cartridges to come to room temperature before opening pouches. Cartridges requiring thermal control should stand at room temperature for 4 hours before use. Cartridges not requiring thermal control may be used after standing 5 minutes at room temperature-an entire box should stand at room temperature for 1 hour.
    - Cartridges should not be exposed to temperatures above 30^0 C (86^0F).
    - Cartridges may be stored at room temperature for 14 days. Do not return cartridges to the refrigerator once they have been at room temperature. Mark the calendar on box with room temperature expiration date.

CAUTION

Cartridges that require thermal control (37°C) must be used with Portable Clinical Analyzer analyzers that have the thermal control feature. A 37° symbol on a black background is printed on the analyzer case to indicate this capability. Cartridges not requiring thermal control can be used with either analyzer.

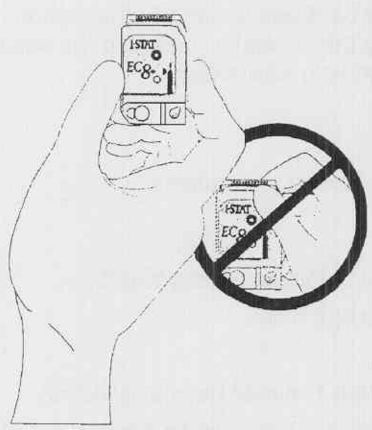


Figure 10-4. Proper Cartridge Handling

3. Remove the cartridge from its pouch.
4. Direct needle, pipette tip, or capillary tube into the sample well. Dispense sample until it reaches the fill mark on cartridge. Figure 10-5 shows the cartridge fill location and cover.

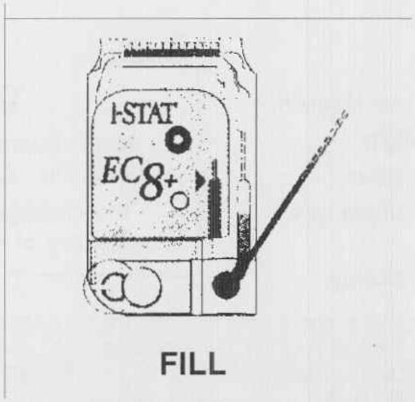


Figure 10-5. Cartridge Fill Location

5. Fold the snap cover over the sample well until it snaps into place (Figure 10-6).

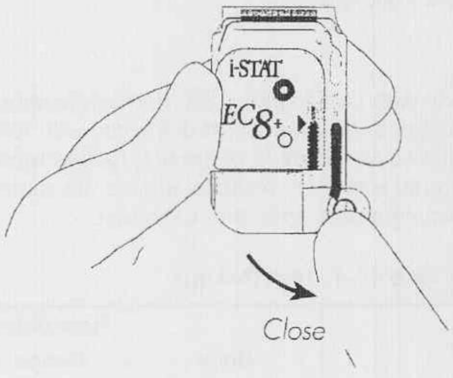
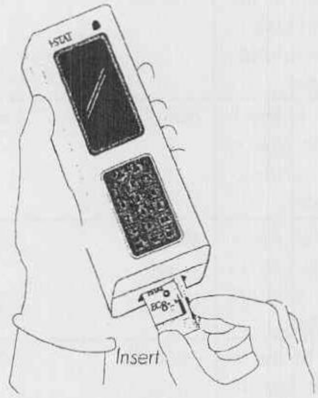


Figure 10-6. Cartridge Cover Location

6. Push the cartridge into the cartridge port on the bottom of the analyzer (Figure 10-7).



Screen display deactivates after 45 seconds to preserve battery life. Results can be redisplayed by pressing the Display key.

Figure 10-7. Cartridge Insertion

10.6.3 Blood Analysis

1. Enter an operator ID up to 7 digits.
2. Repeat the operator ID number for verification.
3. Enter patient ID number up to 12 digits.
4. Repeat patient ID number for verification.
5. Enter blood gas parameters and sample type (when applicable).
6. View the results on the analyzer's display.

CAUTION

- Never attempt to remove a cartridge while the LCK message is displayed.
- The cartridge is medical waste. Dispose of properly.

NOTE
The Portable Clinical Analyzer screen display will deactivate after 45 seconds in order to preserve battery life. Results can be redisplayed by pressing the Display key.

7. Remove the cartridge after the LCK message disappears.

The analyzer is ready for a new cartridge immediately.

10.6.4 Test Results

Test results are displayed numerically, and with bar graphs. Tick marks indicate reference ranges. (Blood gas parameters and their associated calculated values **are not** displayed with reference ranges.) Table 10-1 is a list of test results. Figure 10-8 shows an example of the test results reported. Results that are unreportable due to sensor errors are flagged with "***". Results outside the reportable range are flagged with "<"or">". See Appendix M for the complete data sheets of each test.

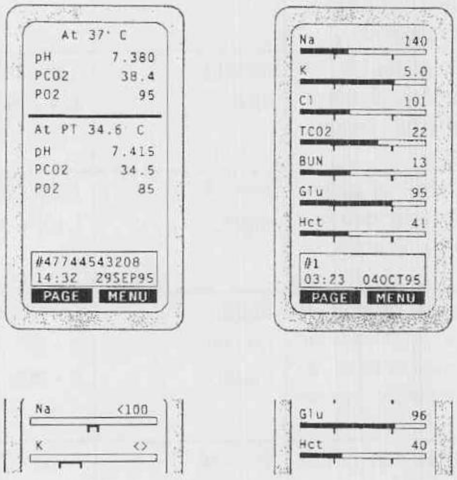
Table 10-1. Test Results

Test	Intended Use	Units	Reportable Range	Reference Range (arterial)	Reference Range (venous)
Sodium/Na	The test for sodium, as part of the i-STAT System, is intended for use in the *in vitro* quantification of arterial, venous, or capillary whole blood.	mmol/L	100 -180	138 -146	138 – 146
Potassium/K	The test for potassium, as part of the i-STAT System, is intended for use in the *in vitro* quantification of arterial, venous, or capillary whole blood.	mmol/L	2.0 - 9.0	3.5 - 4.9	3.5 – 4.9
Chloride/Cl	The test for chloride, as part of the i-STAT System, is intended for use in the in vitro quantification of arterial, venous, or capillary whole blood.	mmol/L	65 -140	98 -109	98 – 109
Glucose/Glu	The test for glucose, as part of the i-STAT System, is intended for use in the *in vitro* quantification of arterial, venous, or capillary whole blood.	Mmol/L mg/dL g/L	1.1 – 38.9 20 – 700 0.20 – 7.00	3.9 – 5.8 70 – 105 0.70 – 1.05	3.9 – 5.8 70 – 105 0.70 – 1.05
Lactate/Lac	The test for lactate, as part of the i-STAT System, is intended for use in the *in vitro* quantification of lactate in arterial, venous, or capillary whole blood.	mmol/L mg/dL	0.30 – 20.00 2.7 – 180.2	0.36 – 1.25 3.2 – 11.3	0.90 – 1.70 8.1 – 15.3

Test	Intended Use	Units	Reportable Range	Reference Range (arterial)	Reference Range (venous)
Creatinine/Crea	The test for creatinine, as part of the i-STAT System, is intended for use in the *in vitro* quantification of creatinine in arterial, venous, or capillary whole blood.	mg/dL µmol/L	0.2 – 20.0 18 – 1768	0.6 – 1.3 53 - 115	0.6 – 1.3 53 - 115
pH	The test for pH, as part of the i-STAT System, is intended for use in the *in vitro* quantification of arterial, venous, or capillary whole blood.		6.5 - 8.0	7.35 -7.45	7.31 – 7.41
PCO_2	The test for PCO_2, as part of the i-STAT System, is intended for use in the *in vitro* quantification of arterial, venous, or capillary whole blood.	mmHg kPa	5 – 130 0.67 – 17.33	35 – 45 4.67 – 6.00	41 – 51 5.47 – 6.80
PO_2	The test for PO_2, as part of the i-STAT System, is intended for use in the *in vitro* quantification of arterial, venous, or capillary whole blood.	mmHg kPa	5 – 800 0.7 – 106.6	80 – 105 10.7 – 14.0	
Ionized Calcium/iCa	The test for ionized calcium, as part of the i-STAT System, is intended for use in the *in vitro* arterial, venous, or capillary whole blood.	mmol/L mg/dL	0.25 - 2.50 1.0 – 10.0	1.12 - 1.32 4.5 – 5.3	1.12 - 1.32 4.5 – 5.3
Urea Nitrogen/BUN Urea	The test for urea nitrogen, as part of the i-STAT System, is intended for use in the *in vitro* quantification of arterial, venous, or capillary whole blood.	mg/dL mmol/L mg/dL	3 – 140 1 – 50 6 - 300	8 – 26 2.9 – 9.4 17 - 56	8 – 26 2.9 – 9.4 17 - 56
Hematocrit/Hct	The test for hematocrit, as part of the i-STAT System, is intended for use in the *in vitro* quantification of arterial, venous, or capillary whole blood.	% PCV Fraction	10 – 75 0.10 – 0.75	38 – 51 0.38 – 0.51	38 – 51 0.38 – 0.51
Celite Activated Clotting Time / ACT	The i-STAT Celite Activated clotting Time (Celite ACT) test cartridge, as part of the i-STAT System, is an *in vitro* diagnostic test used to monitor moderate-and high-level heparin therapy through analysis of arterial and venous whole blood samples.	seconds	50 – 1000	74 – 125	74 - 125
Hemoglobin/Hb*	The test for hematocrit, as part of the i-STAT System, is intended for use in the *in vitro* quantification of arterial, venous, or capillary whole blood.	g/dL g/L mmol/L	3 – 26 34 – 255 2 – 16	12 – 17 120 – 170 7 – 11	12 – 17 120 – 170 7 – 11
TCO_2*	Useful in the assessment of acid-base imbalance (along with pH and PCO_2) and electrolyte imbalance.	mmol/L (mEq/L)	1 - 85	23 - 27	
HCO_3*	Useful in the assessment of acid-base imbalance (along with pH and PCO_2) and electrolyte imbalance.	mmol/L (mEq/L)	1 - 85	22 - 26	
BE_{ecf}*	Excess concentration of base in the average ECF remains virtually constant during acute changes in the PCO_2 and reflects only nonrespiratory component of pH-disturbances.	mmol/L (mEq/L)	(-30) – (+30)	(-2) - (+3)	(-2) - (+3)

Test	Intended Use	Units	Reportable Range	Reference Range (arterial)	Reference Range (venous)
Anion Gap*	Useful for the detection of organic acidosis due to an increase in anions that are difficult to measure. Also, can be used to classify metabolic acidosis into high and normal anion gap tyoes.	mmol/L (mEq/L)	(-10) – (+99)	10 - 20	10 - 20
$_{s}O_2$*	The test for PO_2, as part of the i-STAT System, is intended for use in the *in vitro* quantification of arterial, venous, or capillary whole blood.	%	Not applicable	95 - 98	

*Calculated values



```
At 37' C
pH          7.380
PCO2         38.4
PO2            95

At PT 34.6 C
pH          7.415
PCO2         34.5
PO2            85

#47744543208
14:32  29SEP95
```

```
Na            140
K             5.0
Cl            101
TCO2           22
BUN            13
Glu            95
Hct            41

#1
03:23  04OCT95
```

```
Na           <100
K              <>
```

```
Glu            96
Hct            40
```

Figure 10-8. Reviewing Test Results

10.6.5 Transmit Test Results.

1. Place the Portable Clinical Analyzer in its IR link cradle (Figure 10-3).
2. With results displayed, press the * (asterisk).

The IR link will emit a single high-pitched beep when transmission has been successful; an unsuccessful transmission is indicated by 3 low tone beeps. When this occurs attempt to transmit again.

10.7 Clinical Analyzer Diagnostics

Diagnostics for the Portable Clinical Analyzer is conducted by viewing the Portable Clinical Analyzer display for error/trouble messages in addition to non-electronic failure indications. Table 10-2 lists the indications, conditions, and corrective actions for Portable Clinical Analyzer failures.

Table 10-2. Clinical Analyzer Diagnostics

Indication	Condition	Corrective Action

Indication	Condition	Corrective Action
Temperature Out of Range	The analyzer is recording a temperature outside its operating range.	Move the analyzer to an area within the operating temperature of the test being performed and allow the analyzer to come to the new room temperature. Check the analyzer's temperature reading on the analyzer's Status Page.
New Software Installed	This message appears on the Portable Clinical Analyzer after new software has been installed.	Use Electronic Simulator
"FAIL" shows on display during Electronic Simulator test	Internal failure	Contact IMS Technical Support.
No Screen	Dead batteries	Replace batteries. Batteries are hazardous waste. If you need help disposing of old batteries, contact IMS Technical Support.
IR Link does not transmit.	IR Link/internal Cradle failure .	Contact IMS Technical Support.
SIM	Simulator must be used once every 8 hours.	Use Electronic Simulator.
BAT	Approximately 50 more cartridges can be tested.	Replace batteries soon.
SFT	Software will expire 15 days after SFT is first displayed.	Update software. If you don't have the software update, contact IMS Technical Support.
Date Invalid	The software checks for an unrealistic date.	Check clock on Status Page. If date is correct, call IMS Technical Support.
Dead Batteries	Not enough power to complete testing cycle.	Replace disposable batteries or recharge rechargeable battery.
TEMPERATURE OUT OF RANGE	The analyzer is too warm or too cool, or the room is too warm or too cool.	Check status page. Use another cartridge.
CARTRIDGE ERROR	Analyzer has detected a problem with the calibrant solution	Use another cartridge.
CARTRIDGE TYPE NOT RECOGNIZED	The analyzer could not identify the type of cartridge inserted.	Check software version. Use another cartridge.
CARTRIDGE PREBURST	Calibrant released too soon.	Take care not to press over cartridge label area. Use another cartridge.
SAMPLE POSITIONED SHORT OF FILL MARK	Sample did not reach fill mark.	Tilt cartridge to aid sample flow into sample chamber. Use another cartridge.
SAMPLE POSITIONED BEYOND FILL MARK	Cartridge is overfilled.	Fill new cartridge to fill mark. Press on snap cover tab not over sample well when closing. Use another cartridge.
INSUFFICIENT SAMPLE	Cartridge is under filled or bubbles trapped in sample.	Use another cartridge.
UNABLE TO POSITION SAMPLE	Inadequate seal; sample overflowed well; sample clotted; snap closure left open.	Use another cartridge.
CARTRIDGE NOT INSERTED PROPERLY.	Cartridge not all the way inserted.	Push cartridge straight through door until it will go no further.

Indication	Condition	Corrective Action
ANALYZER ERROR	Analyzer will not function.	Use the Electronic Simulator. If the analyzer passes the simulator check, continue to use. If not, contact IMS Technical Support.
SYSTEM INTERRUPTED	Conditions such as batteries removed before analyzer deactivated when a cartridge is still in analyzer.	Use another cartridge.
CODES 1-14 USUALLY INDICATE A CONDITION RELATED TO THE ENVIRONMENT OR THE STATE OF THE ANALYZER. THESE CONDITIONS ARE USUALLY BENIGN AND GO AWAY AFTER THE NEXT CARTRIDGE OR AN ELECTRONIC SIMULATOR IS INSERTED, OR AFTER THE OFFENDING CONDITION IS CORRECTED.		
1 Dead Batteries	Not enough power to complete testing cycle.	Replace disposable batteries or recharge rechargeable battery.
2 Temperature Out of Range	The analyzer is recording a temperature outside its operating range.	Move the analyzer to an area within the operating temperature of the test being performed and allow the analyzer to come to the new room temperature. Check the analyzer's temperature reading on the analyzer's Status Page.
3 New Software Installed	This message appears on the Portable Clinical Analyzer after new software has been installed.	Use Electronic Simulator
4, 8 Analyzer Interrupted / *Use Another Cartridge*	The analyzer has detected that the last test cycle was not completed. This can happen if the batteries were removed or were making poor contact while a cartridge was still in the analyzer.	Check that the batteries are inserted properly and seated well in the analyzer; check the battery voltage on the analyzer's Status Page and replace the batteries if low. Note: Patient results displayed before this code are valid.
5, 6, 9 Analyzer Interrupted / *Ready for Use*	The Portable Clinical Analyzer is unable to refresh the display. This can happen if power is interrupted before the analyzer powers itself down.	Check that batteries are inserted properly and seated well in analyzer. Batteries that are too short will not make good contact. Check battery voltage on Status Page.
7 Batteries Changed / *Ready for Use*	This is a normal response on the Portable Clinical Analyzer when the batteries are changed after a code 1 has occurred.	Analyzer is ready for use.
10 Temperature in Range / *Ready for Use*	Temperature us back in range after a code 2 on the Portable Clinical Analyzer.	Analyzer is ready for use.
11 Date Invalid	If the date in the real time clock precedes the release date programmed into the application software, code 11 is triggered.	Check the date of the real time clock.
12 Invalid or Expired CLEW	The CLEW standardization set has expired. Date of the real time clock exceeds the expiration date of the CLEW software.	Download a valid CLEW. Check the date of the real time clock.
13 Invalid or Expired CLEW	The CLEW is corrupt or not compatible with the application software (JAMS) or there is no CLEW in the analyzer.	Download a valid CLEW. If this code occurs after a software upgrade and customization is enabled, change the CLEW version in the Customization Profile to the latest version and re-transmit the profile to the analyzer.

Indication	Condition	Corrective Action
14 Analyzer Error	Customization profile is corrupted.	Retransmit the customization profile. If code 14 reoccurs, contact IMS Technical Support for further assistance.
THE FOLLOWING CODES ARE ASSOCIATED WITH THE CARTRIDGE OR FLUID MOVEMENT WITH A CARTRIDGE. THESE CONDITIONS CAN BE OPERATOR OR SAMPLE RELATED. IN MOST CASES, A NEW CARTRIDGE MUST BE USED. IF A CONDITION PERSISTS, ESPECIALLY IF ISOLATED TO ONE ANALYZER, THAN THERE MAY BE AN ANALYZER PROBLEM.		
22 Cartridge Error	This code occurs only for coagulation cartridges if the mixing of sample and reagent is compromised. This can be caused by insufficient or clotted sample.	Use Another Cartridge
24 Cartridge Error	Electrical resistance of the calibrant fluid used to verify the electrolyte concentration is out of specification. This could occur if the calibrant pack was ruptured well before the test allowing evaporation to result in a higher electrolyte concentration. Besides the electrolyte concentration, the electrical resistance of the calibrant fluid is also affected by the temperature and the height and width of the fluid segment over the conductometric sensor. The analyzer accounts for the temperature, but the height and width of the fluid segment can vary from cartridge lot to cartridge lot. The analyzer has been programmed to compensate for height and width differences typical for each lot by maintaining a running average of the resistances measured from the most recent cartridges. Occasionally the differences between two lots is large enough to cause the introduction of a new lot to trigger code 24 on the first few cartridges used. Code 24 will disappear as the running average adjusts. If code 24 persists after more than 3 cartridges on each analyzer, contact IMS Technical Support for further assistance.	Use Another Cartridge
26 Cartridge Error	This code occurs if there was a coagulation specific quality check failure: premature substrate activation, abnormally low levels of substrate, or invalid fluid motion.	Use Another Cartridge
20, 27-29 Cartridge Error 32, 33, 41, 87	These codes identify problems with the cartridge such as calibrant fluid arrival too soon or too late or not at all, or noise in calibrant fluid signals. Codes 20, 27, and 41 can be caused by poor contact which can sometimes be corrected by a pin conditioning procedure.	Use Another Cartridge
42, 43 Cartridge Error	These codes indicate that the conductometric sensor (code 42) or amperometric sensor (code 43) was out of specification. This could be caused by a pre-burst calibrant pack, dirty cartridge contact pads or a dirty connector in the analyzer.	Use Another Cartridge
79-81 Cartridge Error	Bad contact between the thermal probes and the metalization on the back of the chips in the cartridge trigger these codes. Causes are poor metalization of chips, dirt on the metalization, or bent or broken thermal probes in the analyzers.	Use Another Cartridge

Indication	Condition	Corrective Action
21 Cartridge Preburst	This code indicates that the analyzer detected fluid on the sensors before it should have. Possible causes: Poor storage conditions of cartridges (frozen), or mishandling of cartridges (putting pressure in the center of the cartridge), or rerunning used cartridges.	Use Another Cartridge
31, 34, 44 Unable to Position Sample	The analyzer did not detect movement of sample across the sensors. This could be due to not closing the snap closure on the cartridge, to a clot in the sample preventing movement of the sample, or to an aberrant cartridge.	Use Another Cartridge
35,36 Sample Positioned Short of Fill Mark	The cartridge was underfilled. The sample must reach the fill mark.	Use Another Cartridge
30, 37 Sample Positioned Beyond Fill Mark	The cartridge was overfilled. The sample was past the fill mark.	Use another cartridge
38 Insufficient Sample	This is most likely due to insufficient sample in the sample well of the cartridge, but will also be caused by bubbles in the sample.	Use another cartridge and ensure sufficient sample is in the sample well.
47 Cartridge Not Inserted Properly	The Electronic Simulator may not be pushed in all the way.	Reinsert the cartridge or Electronic Simulator. If the problem is recurrent and/or the user is certain the cartridge or Simulator is properly inserted, it may indicate an instrument problem. Contact IMS Technical Support for further assistance.
48 Analyzer Error	This code indicates the cartridge or Electronic Simulator may have been "cocked" when inserted.	Push the cartridge or Simulator straight through the cartridge port. If the problem is recurrent and/or the user is certain the cartridge or Simulator is properly inserted, it may indicate an analyzer problem. Contact IMS Technical Support for further assistance.
THE FOLLOWING CONDITIONS ARE RELATED TO ELECTRONIC OR MECHANICAL FAILURES IN THE ANALYZER.		
50, 51 Analyzer Error	Running a simulator may not detect these problems.	Run the simulator and if the analyzer passes, run a cartridge to see if the code reoccurs. If not, continue to use the analyzer. If the code reoccurs, contact IMS Technical Support for further assistance.
52 Analyzer Error		Run a simulator. If the error occurred while running an ACT cartridge, also run a cartridge. If the code does not reoccur, continue to use the analyzer.

Indication	Condition	Corrective Action
58-62 Analyzer Error	The analyzer usually recovers from these error conditions.	These error conditions can be detected by the Electronic Simulator. If the analyzer passes the Electronic Simulator test continue to use it. If not, check the battery voltage and check the analyzer with another simulator to rule out a simulator problem. If the code persists, contact IMS Technical Support for further assistance.
23, 53, 63, Analyzer Error 65-68, 70, 72-74, 82, 85, 86, 89-94, 96, 97	These are mechanical or electronic failures from which the analyzer may not be able to recover.	Code 70 can occur on the Portable Clinical Analyzer if the user presses the DIS key before the Electronic Simulator is run after a software update. If this happens, reseat the batteries to reset the analyzer and run the Electronic Simulator. For other codes, use the Electronic Simulator twice, then use a cartridge with a sample. If the analyzer passes the simulator check and a quality check code does not occur with the sample, continue to use the analyzer. If code 23 occurs, try the pin conditioning procedure. If the analyzer does not pass the simulator check and/or a quality check code occurs with the sample, contact IMS Technical Support for further assistance.
69 Cartridge Type Not Recognized	1. This code could be due to use of a cartridge type that is not compatible with the version of the software in the analyzer. 2. If the cartridge type has been used successfully before, then the condition may be due to an aberrant cartridge.	1. If this is a new cartridge type, contact IMS Technical Support for a software update. 2. Use another cartridge. If the condition occurs repeatedly, the analyzer may need repair. Code 69 could also be caused by an expired cartridge. Contact IMS Technical Support for further assistance.

Indication	Condition	Corrective Action
69 Cartridge Type Not Recognized	1. This code could be due to use of a cartridge type that is not compatible with the version of the software in the analyzer. 2. If the cartridge type has been used successfully before, then the condition may be due to an aberrant cartridge.	1. If this is a new cartridge type, contact IMS Technical Support for a software update. 2. Use another cartridge. If the condition occurs repeatedly, the analyzer may need repair. Code 69 could also be caused by an expired cartridge. Contact IMS Technical Support for further assistance.

1. The Portable Clinical Analyzer (PCA) comes equipped with an Electronic Simulator, which should be used every 24 hours.
2. Instructions for use of the Electronic Simulator are described in paragraph 10.6.1.
3. The simulator is inserted into the Portable Clinical Analyzer and a "PASS" or "FAIL" message will be displayed. "PASS" indicates an O.K. for continued use. "FAIL" indicates the indicator should not be used. Anytime a "FAIL" message is displayed, the test should be repeated to verify the "FAIL". If "FAIL" repeats, then attempt to operate a cartridge then re-run the electronic simulator. If this fails, then the PCA may require a software update or repair.
4. See Section 12.5.2 for software update instructions.

CHAPTER 11 SECONDARY DISPLAY

11.1 Intended Use and Limitations

Do not operate at temperatures below 0°C or above 35°C.

The Secondary Display provides operator interface functionality beyond that of the Indicator Panel and the Data Entry and Display Panel. It is not essential for running the basic functions of the DDLS, though, it provides the operator with more detailed information regarding the status of the LSTAT subsystems, and provides secondary textual and graphical information of the medical and utility subsystems.

CAUTION

The Secondary Display is configured to be used with the LSTAT. Installation and use of any additional software on the Secondary Display may interfere with proper operation

11.2 Equipment

The Secondary Display is a pen based tablet computer. It is equipped with a Monochrome transflective liquid crystal display (LCD). The display screen uses ambient light to illuminate the LCD and is best suited for outdoor use. The transflective display also has a backlight that can be turned on to illuminate the LCD when the ambient light level is too low. Three display units are currently supported for use with the LSTAT, they are the Fujitsu Stylistic 1000, 1200 and 2300. Appendices H, I and J describe the features and controls of the Stylistic 1000, 1200 and 2300 respectively.

11.3 Secondary Display Setup

11.3.1 Connecting the Secondary Display to LSTAT

1. Obtain the Secondary Display.
2. Connect the Display to the LSTAT receptacle located on the operator/patient interface panel (Figure 11-1) or to the alternative port in the foot compartment (Figure 11-2).

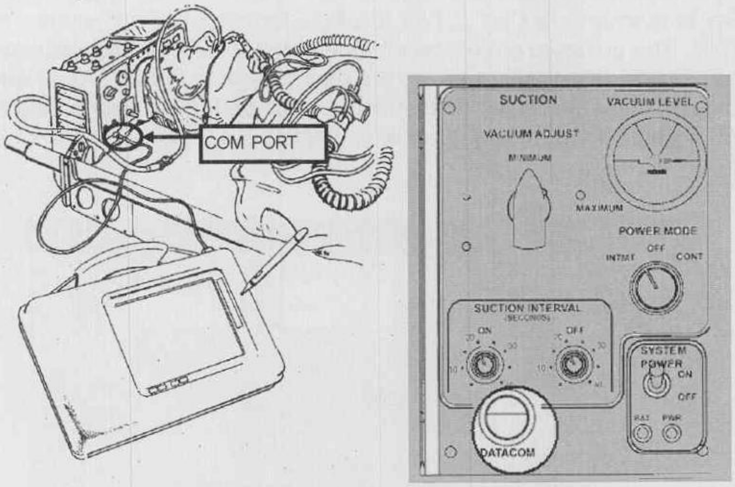


Figure 11-1. Secondary Display Connection to LSTAT

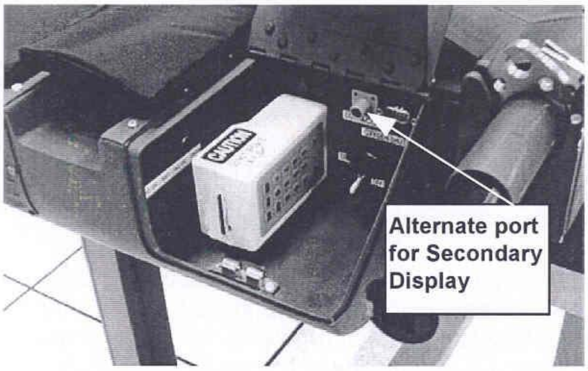


Figure 11-2. Alternate Secondary Display Port

11.3.2 Secondary Display Power-on and Log On

1. Turn on Secondary Display by sliding the main power switch to the ON position (toward the stylus holder).

   The following messages will be displayed during system initialization:

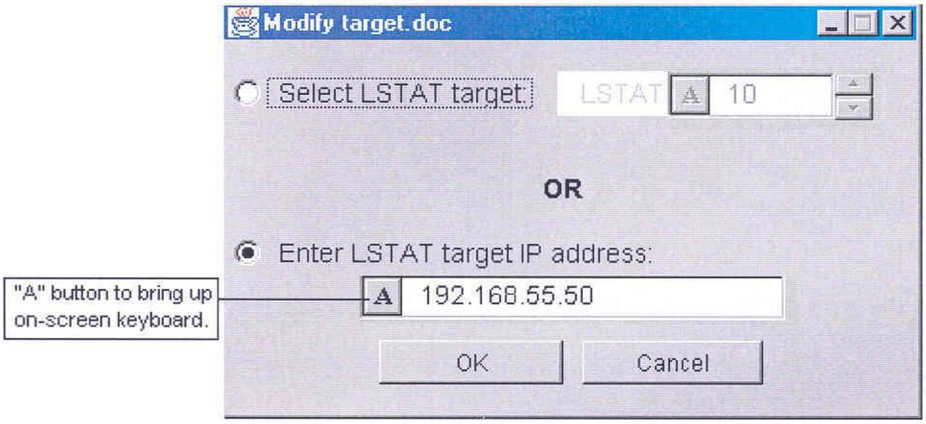
   Stylistic xxxx BIOS Version x.xx
   Copyright xxxx-xxxx Phoenix Technologies Ltd., All Rights Reserved

   As system initialization continues, some additional system configuration messages are displayed and the system boots from the hard drive disk drive.

2. A screen will appear requesting a user name and password. Press the CANCEL button on the screen using the stylus to log onto Windows.

3. When Windows completes boot up, Double Tap the *SDroute* icon with the stylus. A "MODIFY target.doc" window will appear (see Figure 11-3). This will be used to identify with which LSTAT the Secondary Display is to communicate.

4. With the stylus, tap the radio button next to the preferred option for entering the LSTAT ID. The "top" option allows the user to quickly select an LSTAT ID of the form "LSTAT*nn*" where *nn* is a number between 00 and 32767. The up/down arrows next to the number increment/decrement the LSTAT number when tapped. The "bottom" option allows the user to type in the LSTAT IP address using the on-screen keyboard (a regular keyboard may be used if available). (See step 5 below for using the on-screen keyboard.) To obtain the LSTAT ID refer to Section 3.4.3.


Modify target.doc

○ Select LSTAT target: LSTAT 10

OR

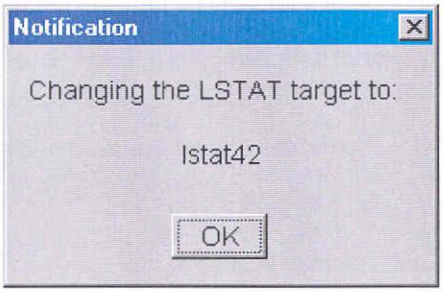
● Enter LSTAT target IP address:

192.168.55.50

Figure 11-3. Modify target.doc window.

5. To use the on-screen keyboard, tap the "A" button on the left of the IP address input field. A keyboard will "pop-up" and characters may be typed (tapped). Tap the "enter" key to input the typed text into the text field. (Note only numeric and decimal point characters will be acceptable in the IP address text field, all others will be deleted from the text when entered. Also the IP address field will not be checked for valid format, i.e. nnn.nnn.nnn.nnn. The target however will be validated, see step 6 below.)

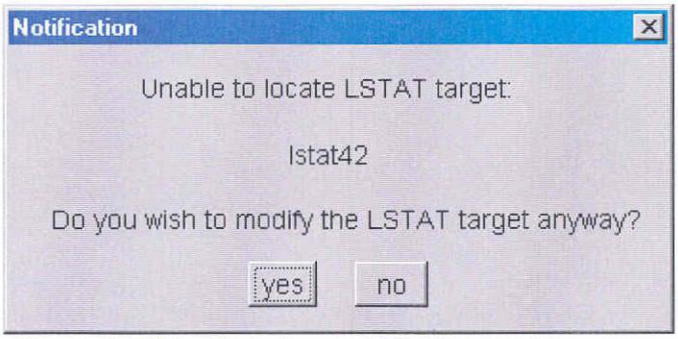
6. Tap OK with the stylus to activate the target selection. (Note: you may tap the Cancel button or the Windows "X" box in the upper right hand corner of the window to cancel a selection and close the window without changing the LSTAT target.) Once the OK button is pressed a dialog box will pop up informing the user of the LSTAT target modification (see Figure 11-4). If the Secondary Display is unable to locate the specified LSTAT target, the dialog box in Figure 11-5 will appear and the user may choose to modify the LSTAT target anyway, or enter a new target (by pressing the "NO" button to return to Figure 11.3). The "OK" button in Figure 11.4 must be clicked before SDRoute will exit. (Note: a valid LSTAT target refers to a system on the network that is running the LSTAT embedded software and is in operational mode.)



Changing the LSTAT target to:

lstat42

Figure 11-4 Modifying LSTAT Target Notification



Unable to locate LSTAT target:

lstat42

Do you wish to modify the LSTAT target anyway?

Figure 11-5 Unable to locate LSTAT target Dialog Box

> **NOTE**
> Steps 3 through 6 may be skipped if the LSTAT ID has been previously established for the current Secondary Display.

NOTE

If a string other than a valid LSTAT*nn* or IP address is entered in the target.doc via a method other that the SDRoute, the string will be displayed in the IP address text field upon startup. However, if an attempt is made to modify the string, all invalid IP address characters will be deleted. If the user presses the "OK" button without modifying the text, the string will be checked as to whether it contains a valid LSTAT

7. Double-tap the *sd* icon to bring up the LSTAT Secondary Display MAIN screen (Figure 11-7).

11.3.3 Screen Format and Navigation

The basic format of the display is the same for all screens. Figure 11-6 illustrates the common format features.

The top bar has space for the Patient ID and Operator ID (Alpha Numeric) and displays the LSTAT date and time*. Below this bar is a set of screen selection buttons. Tap any of these buttons with the Stylus to view a particular subsystem screen. To return to the MAIN screen, tap the MAIN button.

The center portion of the screen displays the patient and system data associated with the particular subsystem screens. This is the area that changes when a different screen is selected.

The rectangular text areas at the bottom, center of the screen are used to display warning and error messages related to the LSTAT system.

The EXIT button in the lower right corner or the Windows "X" box in the upper right hand corner will exit the LSTAT secondary display program and return to Windows.

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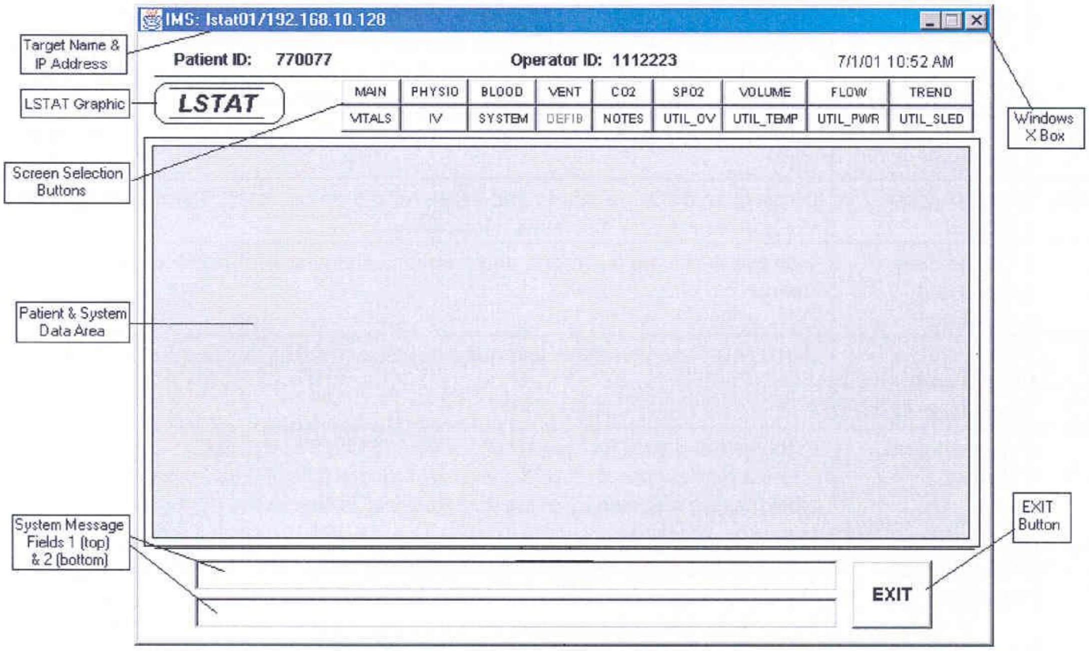
* If the LSTAT time is unavailable for any reason, the Secondary Display will display its local time until the LSTAT time becomes available.



IMS: lstat01/192.168.10.128

Patient ID: 770077

Operator ID: 1112223

7/1/01 10:52 AM

Target Name & IP Address
LSTAT Graphic
LSTAT
Screen Selection Buttons
Patient & System Data Area
System Message Fields 1 (top) & 2 (bottom)
Windows X Box
EXIT Button
MAIN
PHYSIO
BLOOD
VENT
CO2
SPO2
VOLUME
FLOW
TREND
VITALS
IV
SYSTEM
DEFIB
NOTES
UTIL_OV
UTIL_TEMP
UTIL_PWR
UTIL_SLED
EXIT

Figure 11-6. Secondary Display Screen Format

11.3.4 Log Off and Shut Down

1. To exit the program from any screen, tap the EXIT button in the lower right hand corner or the Windows "X" button in the upper right corner. The Windows screen will appear.
2. Tap the Windows **Start** button and then tap the **Shutdown** menu item.
3. Follow the shutdown directions.
4. Turn off the Secondary Display by sliding the switch on the top left of the display unit to the left (Stylistic 1000 & 1200 models only).
5. Replace the Stylus in its holder.

11.4 Secondary Display Screens

Table 11-1 gives a brief description of all of the Secondary Display subsystem screens. Several of the screen formats are described in further detail in the following sections. Each of the available Secondary Display screens is illustrated in this section.

Table 11-1. Display Screen Description

Screen	Subsystem	Description
MAIN Screen	Physiological Monitor	Provides a general overview of critical patient information.
PHYSIO Screen	Physiological Monitor	Provides waveforms for ECG and invasive blood pressures P1 and P2. Numeric values for [*]temperature (T1), Heart rate (HR) and P1 and P2 are also displayed.
BLOOD Screen	Portable Clinical Blood Analyzer	Provides results from Portable Clinical Blood Analyzer once they have been downloaded to the LSTAT system.
VENT Screen	Ventilator	Displays numerical or discrete values for External Air, Sigh, PEEP, Plateau, Pressure Alarms, Ventilation Rate, Inspiration, Tidal Volume (set and delivered) and Air/oxygen mixture. Also PEAK and MEAN airway pressure, Ventilator Mode and Vmin. Paw, airway pressure, is displayed graphically.
CO_2 Screen	Physiological Monitor	Displays CO_2 waveform and numeric values for $EtCO_2$, $INCO_2$ and breath rate (BR).
SpO_2 Screen	Physiological Monitor	Displays an SpO_2 waveform and Pulse Amplitude bar chart. Percent SpO_2 and SpO_2 pulse rate are displayed numerically.
VOLUME Screen	FloTrak flow board and Ventilator	Displays a Volume waveform and numeric values for PEF and Expiratory Volume.
FLOW Screen	FloTrak flow board and Ventilator	Displays a Flow waveform and numeric values for PEF and Expiratory Volume.
TREND Screen	Physiological Monitor	Displays trend data for Heart Rate, NIBP, TEMP, P1, P2, SpO_2, CO_2 and RR/BR (respiration rate/breath rate) for the last 5 hours. The Y-axis for each of the trend plots may be rescaled by using the "Rescale" button to the right of the desired plot.
VITALS Screen	Physiological Monitor	Provides vital signs history for current patient which includes the following: cuff blood pressure, mean blood pressure, pulse rate, temperature in degrees Fahrenheit, SpO_2 and respiration. A time tag is associated with each line of vitals data when it is entered into the list.
IV Screen	IV and Drugs	Numerically displays the following information for all three IV Channels: Pump Status, Infusion Status, Current Rate, Volume Remaining and Volume Infused.
SYSTEM Screen	All	Provides a System overview screen, displaying on/off status for defibrillator, defibrillator rescue, fan, suction, and suction mode and health & safety status for the defibrillator, ventilator, physiological monitor, ISTAT, IV and FloTrak.

---

[*] Temperature units will match the units that were selected on the MAIN screen.

Screen	Subsystem	Description
DEFIB Screen	Defibrillator	Displays the ECG waveform from the Defibrillator data.
NOTES Screen	N/A	Allows operator to input annotations.
UTIL_OV Screen	Electrical Power, Environmental Control & Oxygen	Provides an overview of the LSTAT Temperature, Power and Oxygen subsystems.
UTIL_TEMP Screen	Environmental Control	Provides graphical temperature readings in degrees Celsius for inlet and outlet vents, batteries, head fairing, head, center and foot sled locations. Also displays numeric SMB electronics temperature reading.
UTIL_PWR Screen	Electrical Power	Provides power status for AC/DC converter, HUMVEE power, trickle charge and fan. Displays voltage readings for power bus voltage, PS-1, PS-2, PS-3, PS-4 and PS-5. Battery Level is displayed graphically.
UTIL_SLED Screen	N/A	Provides acceleration, tilt, humidity, pressure, and altitude data.

11.4.1 MAIN Screen

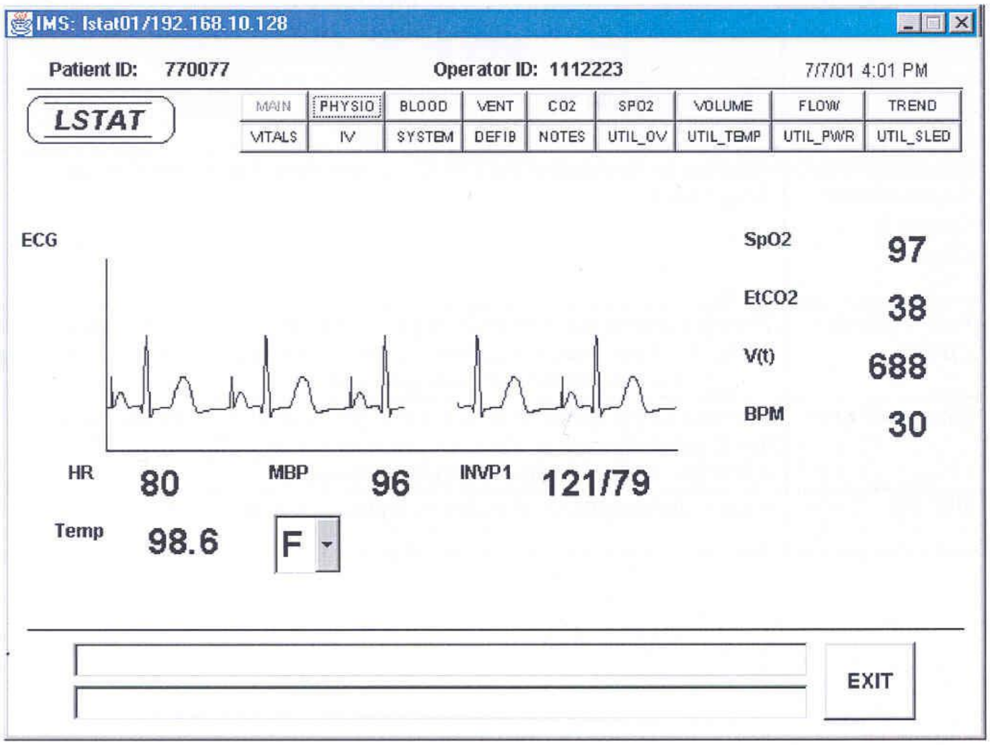
The Main screen (Figure 11-7) displays a collection of patient information:

- ECG waveform
- Heart Rate (HR)
- Mean Blood Pressure (MBP)
- Blood Pressure[*]
- Temperature[**]
- SpO2
- EtCO2
- Tidal Volume (Vt)
- Breaths per Minute (BPM)

---

[*] Blood pressure can be non-invasive, NIBP (cuff), or invasive 1 or 2, INVP1 or INVP2. Depending on which blood pressure reading is valid, display priority will be given to NIBP first, INVP1 next and finally INVP2. The Main Patient Screen blood pressure label will indicate which reading is being displayed.

[**] Temperature units are selectable in degrees Celsius or Fahrenheit using the pull-down menu to the right of the temperature value.



Patient ID: 770077
Operator ID: 1112223
7/7/01 4:01 PM

SpO2 97
EtCO2 38
V(t) 688
BPM 30

HR 80
MBP 96
INVP1 121/79
Temp 98.6 F

Figure 11-7. MAIN Screen

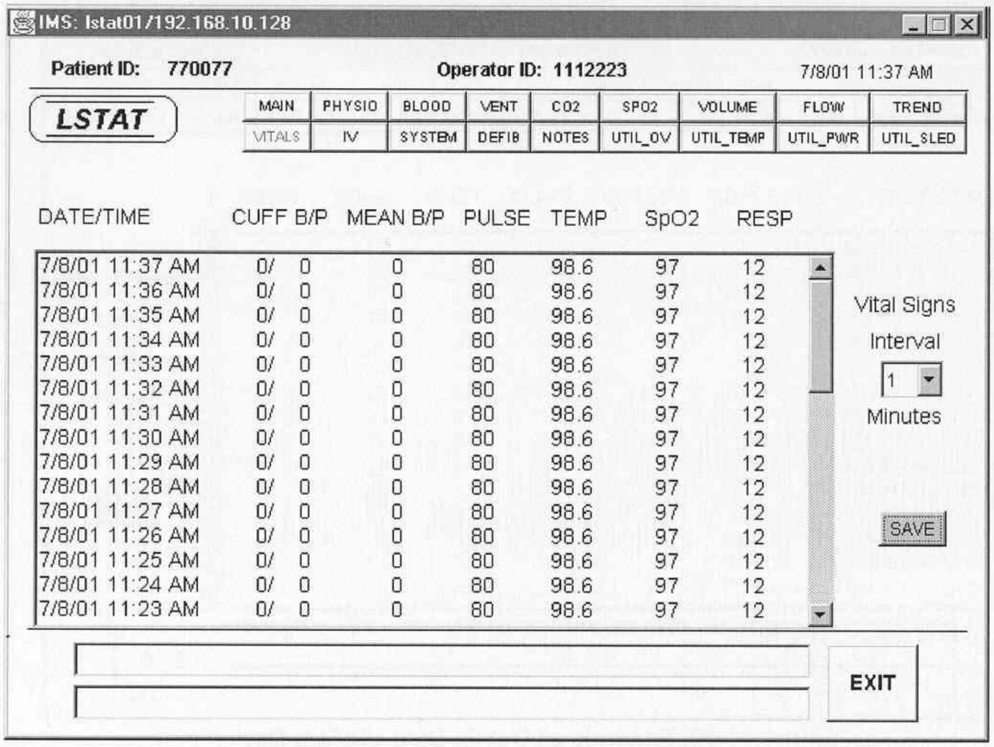
11.4.2 VITALS Screen

The VITALS screen (Figure 11-8) displays a vital signs history for the current patient for up to 8 hours. Vital sign readings of cuff blood pressure, mean blood pressure, pulse rate, temperature in degrees Fahrenheit, SpO_2 and respiration are derived from the Physiological Monitor messages, time tagged and recorded once per minute by the DDLS. The time interval of the displayed list is selectable via the vital signs interval pull-down menu on the mid-right side of the screen. Intervals of 1, 2, 5, 10, 15 and 30 minutes are available.

Vital signs data is reinitialized when the patient ID is changed or when the LSTAT is rebooted. If the Physiological Monitor is powered down or data is missing for any time interval, a gap (blank line) will be displayed in the list to indicate the missing data (see Figure 11-9). If data is not received within a minute, the vitals history is grayed out and an information message is displayed in Message Field 1 to inform the operator that the LSTAT is not responding as expected (see Figure 11-10).

Vital signs data may be saved to the local disk by tapping the "SAVE" button. The list will be saved to a "VitalSigns" folder on the Desktop of the local computer. The name for the file is created using the timestamp of the latest entry in the vital signs list in the form MMddhhmm.txt where MM = 2 digit month number, dd = 2 digit day, hh = 2 digit hour (24-hr format) and mm = 2 digit minute value. The file may be viewed using any ASCII text editor, the default is Notepad on most Windows machines[+]. Figure 11-8 illustrates the Secondary Display VITALS screen, while Figure 11-11 illustrates the vital signs text output format.

[+] You may need to change the page orientation to landscape rather than portrait to align the columns of data correctly. (Figure 11-11 has been reduced in size for the purpose of this document.)

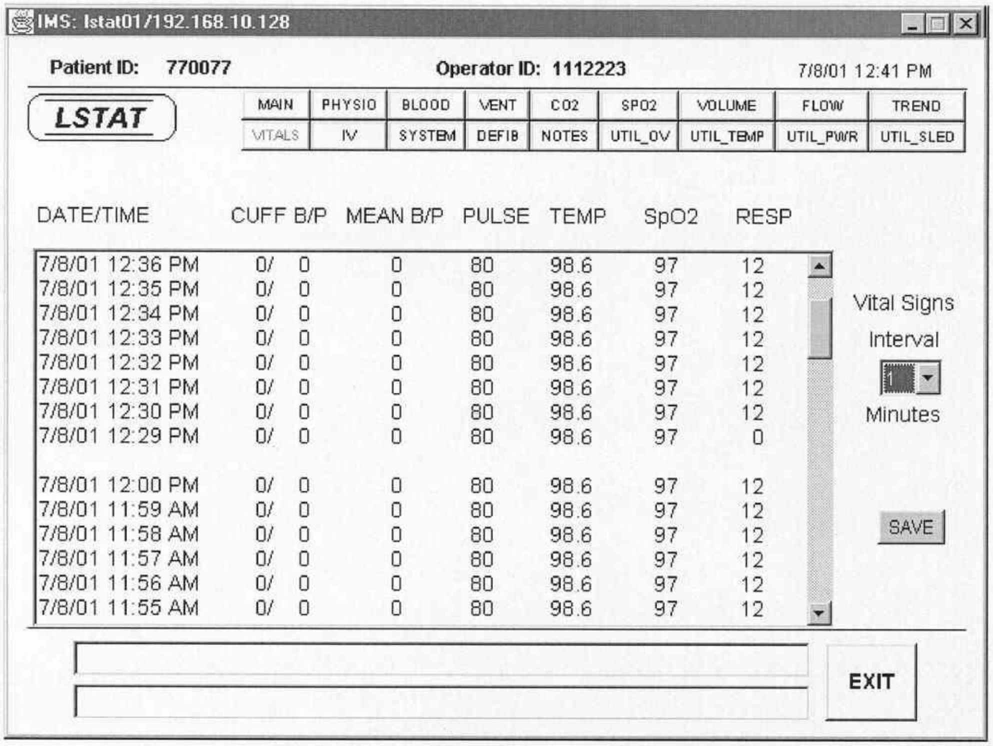

IMS: lstat01/192.168.10.128
LSTAT
MAIN
PHYSIO
BLOOD
VENT
CO2
SPO2
VOLUME
FLOW
TREND
VITALS
IV
SYSTEM
DEFIB
NOTES
UTIL_OV
UTIL_TEMP
UTIL_PWR
UTIL_SLED
SAVE
EXIT

Patient ID: 770077 **Operator ID:** 1112223 7/8/01 11:37 AM

DATE/TIME	CUFF B/P	MEAN B/P	PULSE	TEMP	SpO2	RESP
7/8/01 11:37 AM	0/ 0	0	80	98.6	97	12
7/8/01 11:36 AM	0/ 0	0	80	98.6	97	12
7/8/01 11:35 AM	0/ 0	0	80	98.6	97	12
7/8/01 11:34 AM	0/ 0	0	80	98.6	97	12
7/8/01 11:33 AM	0/ 0	0	80	98.6	97	12
7/8/01 11:32 AM	0/ 0	0	80	98.6	97	12
7/8/01 11:31 AM	0/ 0	0	80	98.6	97	12
7/8/01 11:30 AM	0/ 0	0	80	98.6	97	12
7/8/01 11:29 AM	0/ 0	0	80	98.6	97	12
7/8/01 11:28 AM	0/ 0	0	80	98.6	97	12
7/8/01 11:27 AM	0/ 0	0	80	98.6	97	12
7/8/01 11:26 AM	0/ 0	0	80	98.6	97	12
7/8/01 11:25 AM	0/ 0	0	80	98.6	97	12
7/8/01 11:24 AM	0/ 0	0	80	98.6	97	12
7/8/01 11:23 AM	0/ 0	0	80	98.6	97	12

Vital Signs Interval 1 Minutes

Figure 11-8. VITALS Screen

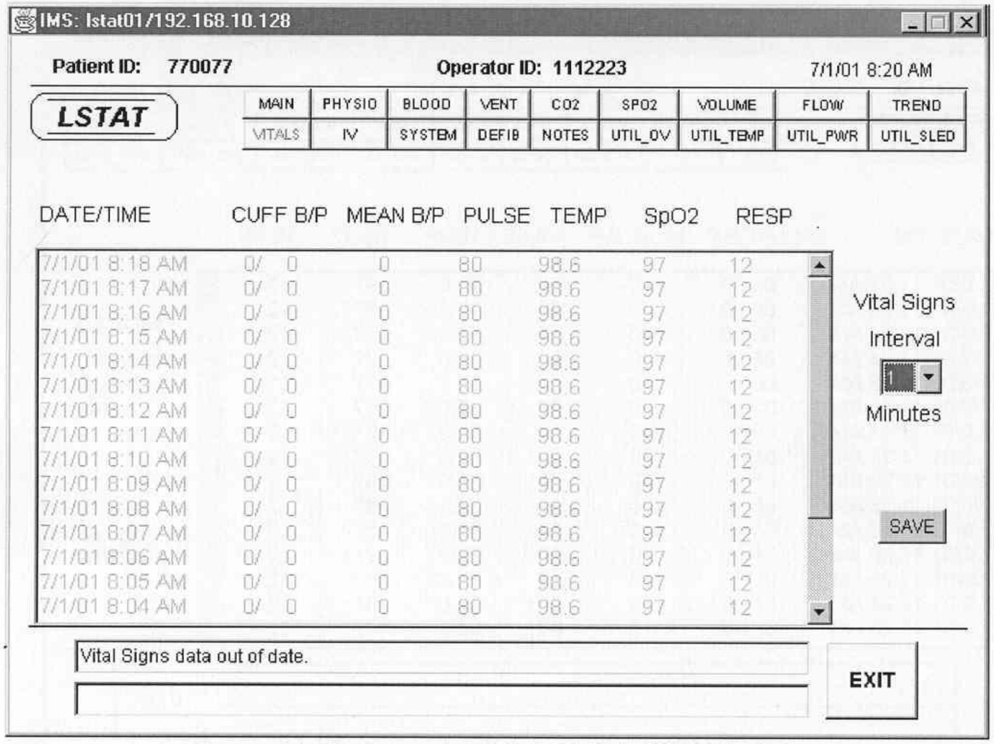

IMS: lstat01/192.168.10.128
LSTAT
MAIN
PHYSIO
BLOOD
VENT
CO2
SPO2
VOLUME
FLOW
TREND
VITALS
IV
SYSTEM
DEFIB
NOTES
UTIL_OV
UTIL_TEMP
UTIL_PWR
UTIL_SLED
SAVE
EXIT

Patient ID: 770077 **Operator ID:** 1112223 7/8/01 12:41 PM

DATE/TIME	CUFF B/P	MEAN B/P	PULSE	TEMP	SpO2	RESP
7/8/01 12:36 PM	0/ 0	0	80	98.6	97	12
7/8/01 12:35 PM	0/ 0	0	80	98.6	97	12
7/8/01 12:34 PM	0/ 0	0	80	98.6	97	12
7/8/01 12:33 PM	0/ 0	0	80	98.6	97	12
7/8/01 12:32 PM	0/ 0	0	80	98.6	97	12
7/8/01 12:31 PM	0/ 0	0	80	98.6	97	12
7/8/01 12:30 PM	0/ 0	0	80	98.6	97	12
7/8/01 12:29 PM	0/ 0	0	80	98.6	97	0
7/8/01 12:00 PM	0/ 0	0	80	98.6	97	12
7/8/01 11:59 AM	0/ 0	0	80	98.6	97	12
7/8/01 11:58 AM	0/ 0	0	80	98.6	97	12
7/8/01 11:57 AM	0/ 0	0	80	98.6	97	12
7/8/01 11:56 AM	0/ 0	0	80	98.6	97	12
7/8/01 11:55 AM	0/ 0	0	80	98.6	97	12

Vital Signs Interval 1 Minutes

Figure 11-9. Example of "Gaps" In VITALS Data


IMS: lstat01/192.168.10.128
LSTAT
MAIN
PHYSIO
BLOOD
VENT
CO2
SPO2
VOLUME
FLOW
TREND
VITALS
IV
SYSTEM
DEFIB
NOTES
UTIL_OV
UTIL_TEMP
UTIL_PWR
UTIL_SLED
SAVE
EXIT

Patient ID: 770077 **Operator ID:** 1112223 7/1/01 8:20 AM

DATE/TIME	CUFF B/P	MEAN B/P	PULSE	TEMP	SpO2	RESP
7/1/01 8:18 AM	0/ 0	0	80	98.6	97	12
7/1/01 8:17 AM	0/ 0	0	80	98.6	97	12
7/1/01 8:16 AM	0/ 0	0	80	98.6	97	12
7/1/01 8:15 AM	0/ 0	0	80	98.6	97	12
7/1/01 8:14 AM	0/ 0	0	80	98.6	97	12
7/1/01 8:13 AM	0/ 0	0	80	98.6	97	12
7/1/01 8:12 AM	0/ 0	0	80	98.6	97	12
7/1/01 8:11 AM	0/ 0	0	80	98.6	97	12
7/1/01 8:10 AM	0/ 0	0	80	98.6	97	12
7/1/01 8:09 AM	0/ 0	0	80	98.6	97	12
7/1/01 8:08 AM	0/ 0	0	80	98.6	97	12
7/1/01 8:07 AM	0/ 0	0	80	98.6	97	12
7/1/01 8:06 AM	0/ 0	0	80	98.6	97	12
7/1/01 8:05 AM	0/ 0	0	80	98.6	97	12
7/1/01 8:04 AM	0/ 0	0	80	98.6	97	12

Vital Signs Interval: 1 Minutes

Vital Signs data out of date.

Figure 11-10. Example of Out Of Date VITALS Data

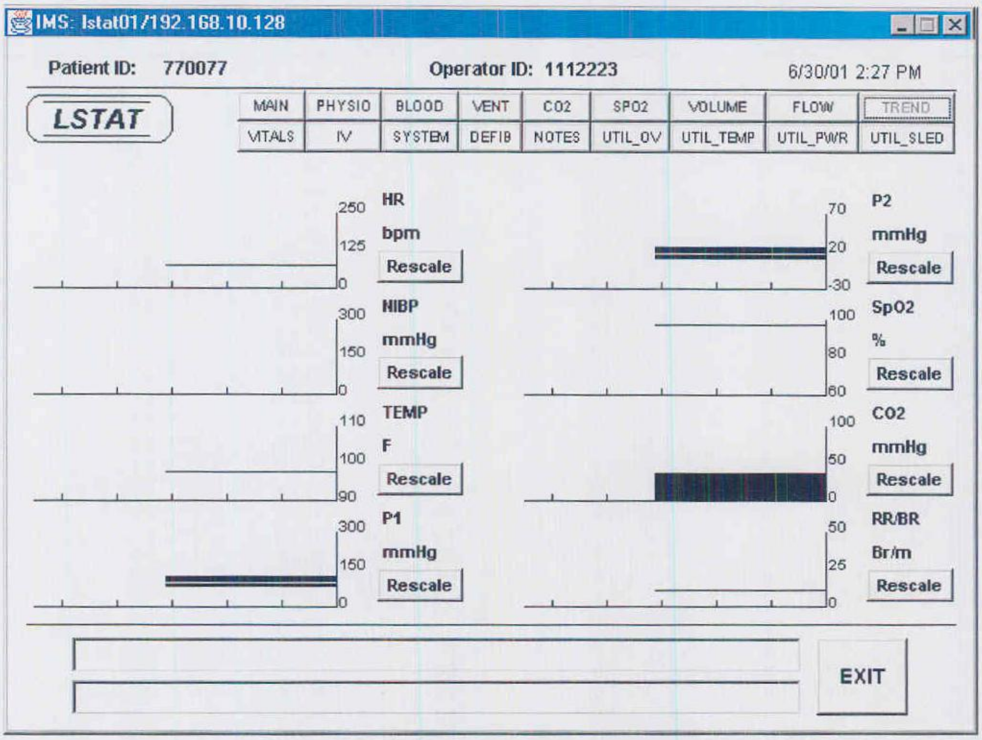
```
Patient:  770077
Operator: 1112223

DATE/TIME               CUFF B/P         MEAN B/P       PULSE       TEMP          SpO2         RESP
7/8/01 11:37 AM         0/    0             0           80         98.6           97            12
7/8/01 11:36 AM         0/    0             0           80         98.6           97            12
7/8/01 11:35 AM         0/    0             0           80         98.6           97            12
7/8/01 11:34 AM         0/    0             0           80         98.6           97            12
7/8/01 11:33 AM         0/    0             0           80         98.6           97            12
7/8/01 11:32 AM         0/    0             0           80         98.6           97            12
7/8/01 11:31 AM         0/    0             0           80         98.6           97            12
7/8/01 11:30 AM         0/    0             0           80         98.6           97            12
7/8/01 11:29 AM         0/    0             0           80         98.6           97            12
7/8/01 11:28 AM         0/    0             0           80         98.6           97            12
7/8/01 11:27 AM         0/    0             0           80         98.6           97            12
7/8/01 11:26 AM         0/    0             0           80         98.6           97            12
7/8/01 11:25 AM         0/    0             0           80         98.6           97            12
7/8/01 11:24 AM         0/    0             0           80         98.6           97            12
7/8/01 11:23 AM         0/    0             0           80         98.6           97            12
7/8/01 11:22 AM         0/    0             0           80         98.6           97            12
7/8/01 11:21 AM         0/    0             0           80         98.6           97            12
7/8/01 11:20 AM         0/    0             0           80         98.6           97            12
7/8/01 11:19 AM         0/    0             0           80         98.6           97            12
7/8/01 11:18 AM         0/    0             0           80         98.6           97            12
7/8/01 11:17 AM         0/    0             0           80         98.6           97            12
7/8/01 11:16 AM         0/    0             0           80         98.6           97            12
7/8/01 11:15 AM         0/    0             0           80         98.6           97            12
7/8/01 11:14 AM         0/    0             0           80         98.6           97            12
7/8/01 11:13 AM         0/    0             0           80         98.6           97            12
7/8/01 11:12 AM         0/    0             0           80         98.6           97            12
7/8/01 11:11 AM         0/    0             0           80         98.6           97            12
7/8/01 11:10 AM         0/    0             0           80         98.6           97            12
7/8/01 11:09 AM         0/    0             0           80         98.6           97            12
7/8/01 11:08 AM         0/    0             0           80         98.6           97            12
7/8/01 11:07 AM         0/    0             0           80         98.6           97            12
7/8/01 11:06 AM         0/    0             0           80         98.6           97            12
7/8/01 11:05 AM         0/    0             0           80         98.6           97            12
7/8/01 11:04 AM         0/    0             0           80         98.6           97            12
7/8/01 11:03 AM         0/    0             0           80         98.6           97            12
7/8/01 11:02 AM         0/    0             0           80         98.6           97            12
7/8/01 11:01 AM         0/    0             0           80         98.6           97            12
7/8/01 11:00 AM         0/    0             0           80         98.6           97            12
7/8/01 10:59 AM         0/    0             0           80         98.6           97            12
7/8/01 10:58 AM         0/    0             0           80         98.6           97            12
```

Figure 11-11 Example of VitalSigns\MMddhhmm.txt Output Format

11.4.3 TREND Screen

The TREND screen (Figure 11-12) displays trend values averaged over two minute intervals for heart rate, NIBP, temperature, invasive blood pressures P1 & P2, SpO_2, CO_2, and respiration/breath rate. The Physiological Monitor generates the trend data and the Secondary Display emulates its trend waveform displays.

Trend waveforms are reinitialized when the patient ID is changed or when the LSTAT is shutdown. If the Physiological Monitor is turned off or data is missing for any reason, a gap will be displayed in the waveform to indicate the missing data (see Figure 11-13). If data is not received within three minutes, an information message will be displayed in Message Field 1 to inform the operator that the LSTAT is not responding as expected (see Figure 11-14).


IMS: lstat01/192.168.10.128

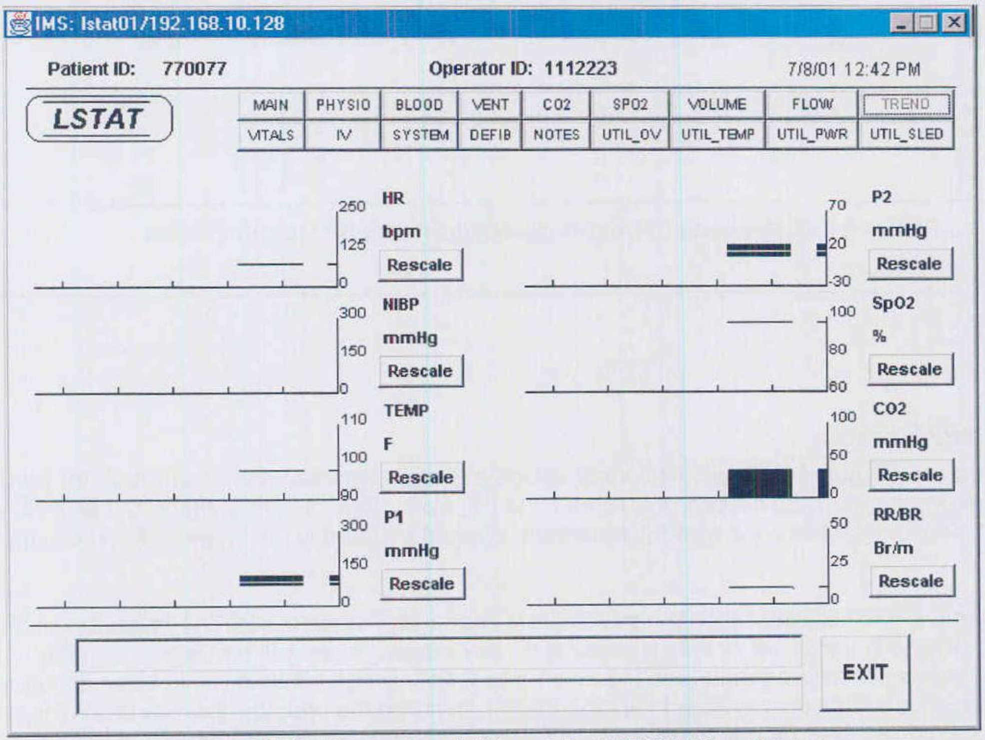
Patient ID: 770077

Operator ID: 1112223

6/30/01 2:27 PM

LSTAT
MAIN
PHYSIO
BLOOD
VENT
CO2
SPO2
VOLUME
FLOW
TREND
VITALS
IV
SYSTEM
DEFIB
NOTES
UTIL_OV
UTIL_TEMP
UTIL_PWR
UTIL_SLED
HR
bpm
250
125
0
Rescale
NIBP
mmHg
300
150
0
Rescale
TEMP
F
110
100
90
Rescale
P1
mmHg
300
150
0
Rescale
P2
mmHg
70
20
-30
Rescale
SpO2
%
100
80
60
Rescale
CO2
mmHg
100
50
0
Rescale
RR/BR
Br/m
50
25
0
Rescale
EXIT

Figure 11-12. TREND Screen


IMS: lstat01/192.168.10.128

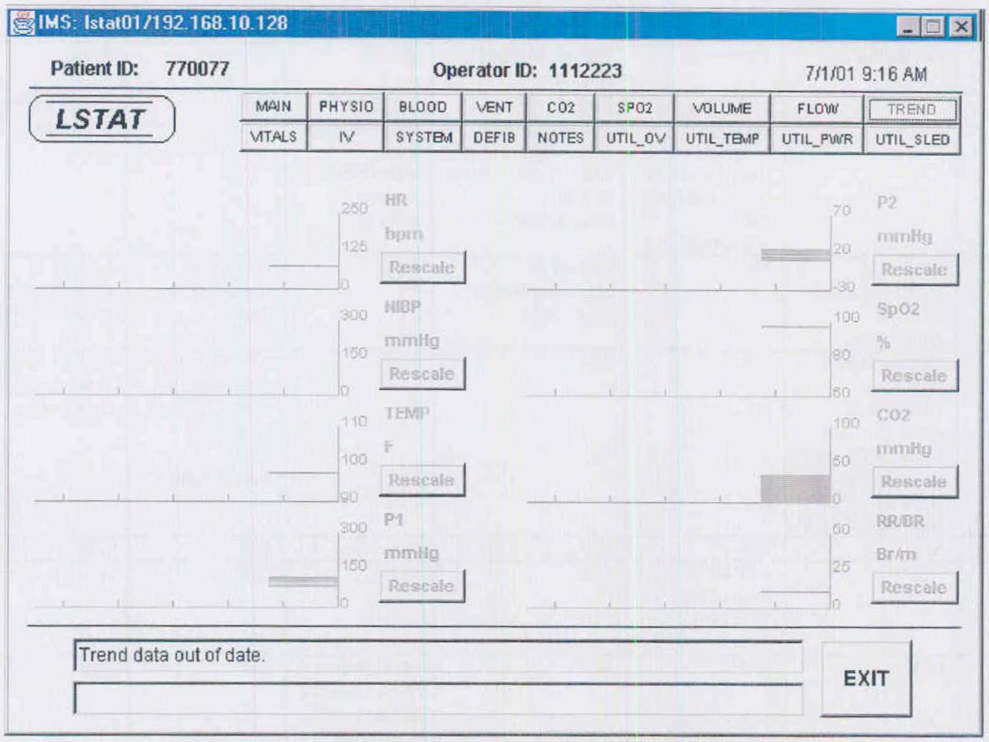
Patient ID: 770077

Operator ID: 1112223

7/8/01 12:42 PM

LSTAT
MAIN
PHYSIO
BLOOD
VENT
CO2
SPO2
VOLUME
FLOW
TREND
VITALS
IV
SYSTEM
DEFIB
NOTES
UTIL_OV
UTIL_TEMP
UTIL_PWR
UTIL_SLED
HR
bpm
250
125
0
Rescale
NIBP
mmHg
300
150
0
Rescale
TEMP
F
110
100
90
Rescale
P1
mmHg
300
150
0
Rescale
P2
mmHg
70
20
-30
Rescale
SpO2
%
100
80
60
Rescale
CO2
mmHg
100
50
0
Rescale
RR/BR
Br/m
50
25
0
Rescale
EXIT

Figure 11-13. Example of "Gaps" in TREND Waveforms


IMS: lstat01/192.168.10.128
LSTAT
MAIN
PHYSIO
BLOOD
VENT
CO2
SPO2
VOLUME
FLOW
TREND
VITALS
IV
SYSTEM
DEFIB
NOTES
UTIL_OV
UTIL_TEMP
UTIL_PWR
UTIL_SLED
250
125
0
HR
bpm
Rescale
300
150
0
NIBP
mmHg
Rescale
110
100
90
TEMP
F
Rescale
300
150
0
P1
mmHg
Rescale
70
20
-30
P2
mmHg
Rescale
100
80
60
SpO2
%
Rescale
100
50
0
CO2
mmHg
Rescale
50
25
0
RR/BR
Br/m
Rescale
EXIT

Patient ID: 770077

Operator ID: 1112223

7/1/01 9:16 AM

Trend data out of date.

Figure 11-14. Example of Out of Date Trend Screen

11.4.4 System Screen

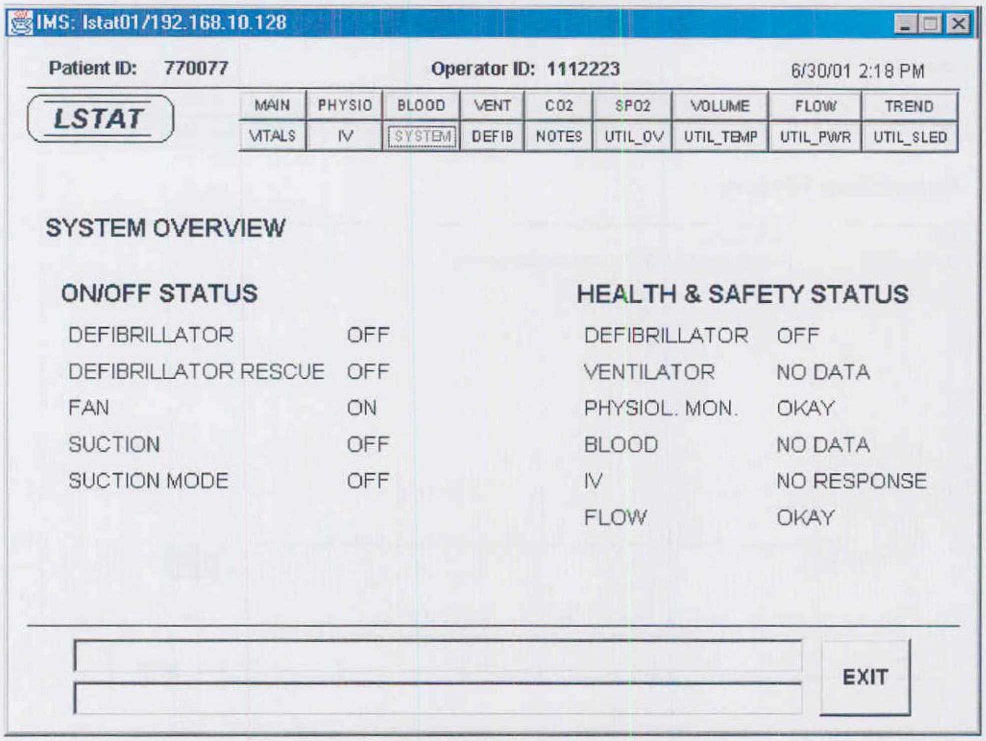
The System Screen (Figure 11-15) displays an overview of the on/off status of LSTAT subsystems as well as LSTAT subsystem health and safety information. Table 11-2 describes the conditions for the on/off status and Table 11-3 describes the health and safety responses.

Table 11-2. System On/Off Status

	Defibrillator	Defibrillator Rescue	Fan	Suction	Suction Mode
On	Defibrillator is powered on.	Defibrillator is ready to rescue. Flashes "On" when Defibrillator is announcing "Stand clear, press flashing button to rescue."	Fan is powered on.	Suction flag is 0 OR Suction flag is 1 AND Suction Mode value is 0.	Suction Mode = INTERMITTENT Suction Mode = CONTINUOUS
Off	Defibrillator is powered off.	Defibrillator is not ready to rescue.	Fan is powered off.	Suction flag is 1 AND Suction Mode value is 1.	Suction Mode = OFF

Table 11-3. System Screen Health & Safety Status

	Defibrillator	**Ventilator**	**Physiological Monitor**	**Blood**	**IV**	**Flow**
No Data	N/A	LSTAT is not receiving Ventilator data. (Vent. is off or error in data transmission.)	LSTAT is not receiving Phys. Mon. data. (Phys. Mon. is off or error in data transmission.)	No ISTAT records have been transmitted for this patient.	N/A	Same as No Response.
Okay	LSTAT is receiving data from Defibrillator.	N/A	LSTAT is receiving Phys. Mon. data.	N/A	LSTAT is receiving IV data.	LSTAT is receiving data from Flow Board.
No Response	LSTAT is not receiving Defibrillator data. (Defib is off or Defib was powered on before LSTAT was initialized.)	N/A	N/A	N/A	LSTAT is not receiving IV data. (IV is off or error in data transmission.)	LSTAT is not receiving Flow Board data.
Off	N/A	N/A	N/A	N/A	N/A	N/A
Data	N/A	LSTAT is receiving Ventilator data.	N/A	N/A	N/A	N/A
Old Data	N/A	N/A	N/A	Most recent ISTAT record is more than 5 minutes old.	N/A	N/A
New Data	N/A	N/A	N/A	ISTAT record has been transmitted within the last 5 minutes.	N/A	N/A


IMS: lstat01/192.168.10.128
LSTAT
MAIN
PHYSIO
BLOOD
VENT
CO2
SPO2
VOLUME
FLOW
TREND
VITALS
IV
SYSTEM
DEFIB
NOTES
UTIL_OV
UTIL_TEMP
UTIL_PWR
UTIL_SLED
EXIT

Patient ID: 770077

Operator ID: 1112223

6/30/01 2:18 PM

SYSTEM OVERVIEW

ON/OFF STATUS

DEFIBRILLATOR	OFF
DEFIBRILLATOR RESCUE	OFF
FAN	ON
SUCTION	OFF
SUCTION MODE	OFF

HEALTH & SAFETY STATUS

DEFIBRILLATOR	OFF
VENTILATOR	NO DATA
PHYSIOL. MON.	OKAY
BLOOD	NO DATA
IV	NO RESPONSE
FLOW	OKAY

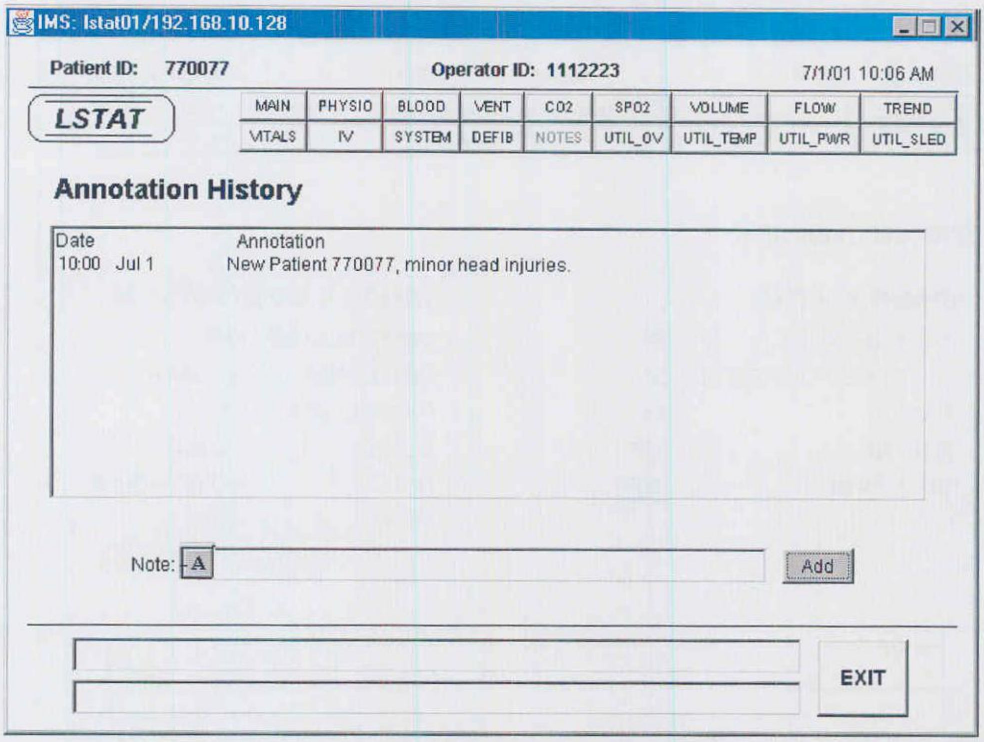
Figure 11-15. SYSTEM Screen

11.4.5 Notes Screen

The NOTES screen (Figure 11-16) is the only Secondary Display screen that permits user input. Once a note has been added to the annotation history, it cannot be edited nor deleted. The annotation history is cleared when the patient ID is changed on the LSTAT.

To enter data:

1. Tap the *NOTES* screen selection button. The ANNOTATION HISTORY screen will appear.
2. Tap the "*A*" box to the right of the word "Note" to bring up the on-screen keyboard.
3. Enter text by tapping the desired keys on the on-screen keyboard.
4. Tap OK to remove the keyboard and enter text into the Note: text field on the Secondary Display.
5. Tap *ADD* on the Notes screen to add the note to the annotation history list. A time tag will be pre-pended to the note when it is added to the list.
6. To leave the NOTES screen, tap a different screen selection button.



Patient ID: 770077 **Operator ID:** 1112223 7/1/01 10:06 AM

Annotation History

Date	Annotation
10:00 Jul 1	New Patient 770077, minor head injuries.

Figure 11-16. NOTES Screen

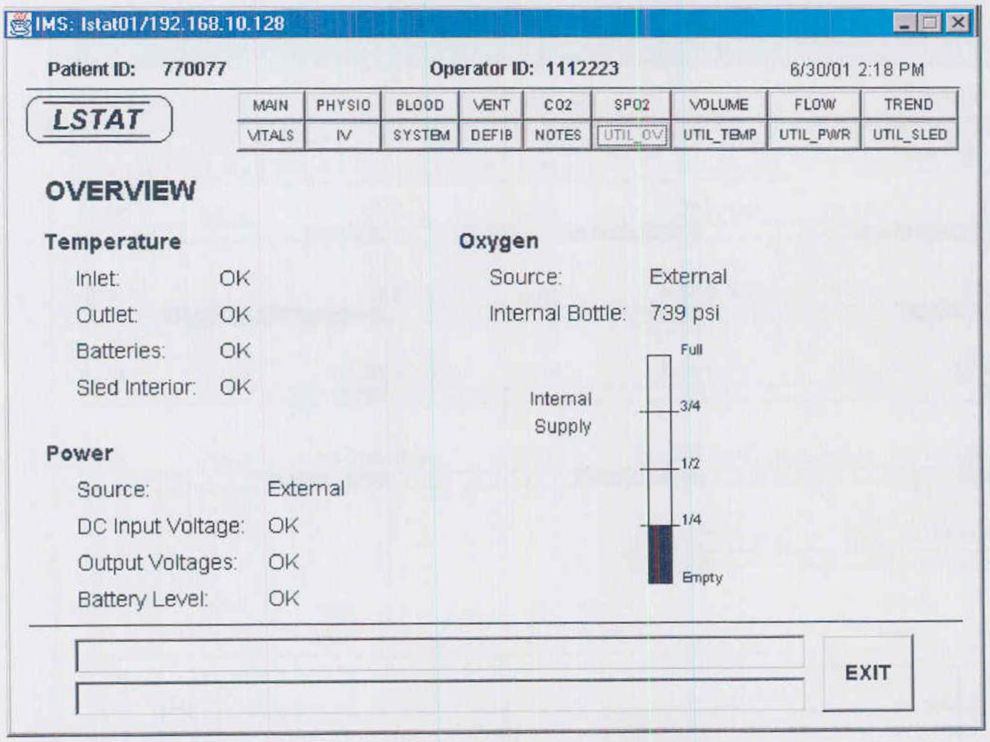
11.4.6 UTIL_OV Screen

The UTIL_OV screen (Figure 11-17) displays an overview of the LSTAT Oxygen, Temperature and Power subsystems. Table 11-4 UTIL_OV Screen Discrete Description describes the conditions for particular results.

Table 11-4 UTIL_OV Screen Discrete Description

Parameter	Result	Condition
Inlet Temperature	OK	Inlet temperature reading within range limits (-25C < temp < 80C).
	LOW	Inlet temperature reading <= lower range limit (-25 C).
	HIGH	Inlet temperature reading >= upper range limit (80 C).
Outlet Temperature	OK	Outlet temperature reading within range limits (-25C < temp < 80C).
	LOW	Outlet temperature reading <= lower range limit (-25 C).
	HIGH	Outlet temperature reading >= upper range limit (80 C).
Battery Temperature	OK	Battery 1 and battery 2 temperature readings within range limits (-25C < temp < 80C).
	LOW	Battery 1 or battery 2 temperature reading <= lower range limit (-25 C).
	HIGH	Battery 1 or battery 2 temperature reading >= upper range limit (80 C).
Sled Interior Temperature	OK	Center sled compartment **and** Foot sled compartment **and** head fairing sled compartment **and** head end bay sled compartment temperature readings are **all** within range limits (-25C < temp < 80C).
	LOW	Battery 1 or battery 2 temperature reading <= lower range limit (-25 C).
	HIGH	Battery 1 or battery 2 temperature reading >= upper

Parameter	Result	Condition
		range limit (80 C).
Power Source	External	Humvee power is on (>=6 volts) OR AC/DC converter is on (Note: AC/DC converter uses inverted logic, so a high bit indicates off.)
	Internal	Humvee power is off (<6 volts) AND AC/DC converter is off. (See above Note.)
DC Input Voltage	OK	Humvee power is on (>=6 volts) OR Power Bus voltage >=6 volts.
	NOT OK	Humvee power is off (<6 volts) AND Power Bus voltage <6 volts.
Output Voltages	OK	All of PS1, PS2, PS3, PS4 and PS5 values are within their acceptable ranges.
	LOW	One or more of PS1, PS2, PS3, PS4 or PS5 values are > than their respective lower limits.
	HIGH	One or more of PS1, PS2, PS3, PS4 or PS5 values are < than their respective upper limits.
	NOT OK	One or more of PS1, PS2, PS3, PS4 or PS5 values are > than their respective lower limits AND One or more of PS1, PS2, PS3, PS4 or PS5 values are < than their respective upper limits.
Battery Level	OK	Battery level signal indicates anything above LOW.
	LOW	Battery level signal indicates LOW.
Oxygen Source	Internal	Oxygen source signal indicates 0 AND at least 1 oxygen level LED is on.
	External	Oxygen source signal indicates 1 AND oxygen pressure > 0.
	Off	Oxygen source signal indicates 1 AND oxygen pressure <= 0.


IMS: lstat01/192.168.10.128
LSTAT
MAIN
PHYSIO
BLOOD
VENT
CO2
SPO2
VOLUME
FLOW
TREND
VITALS
IV
SYSTEM
DEFIB
NOTES
UTIL_OV
UTIL_TEMP
UTIL_PWR
UTIL_SLED
Internal Supply
Full
3/4
1/2
1/4
Empty
EXIT

Patient ID: 770077
Operator ID: 1112223
6/30/01 2:18 PM

OVERVIEW

Temperature

Inlet: OK
Outlet: OK
Batteries: OK
Sled Interior: OK

Power

Source: External
DC Input Voltage: OK
Output Voltages: OK
Battery Level: OK

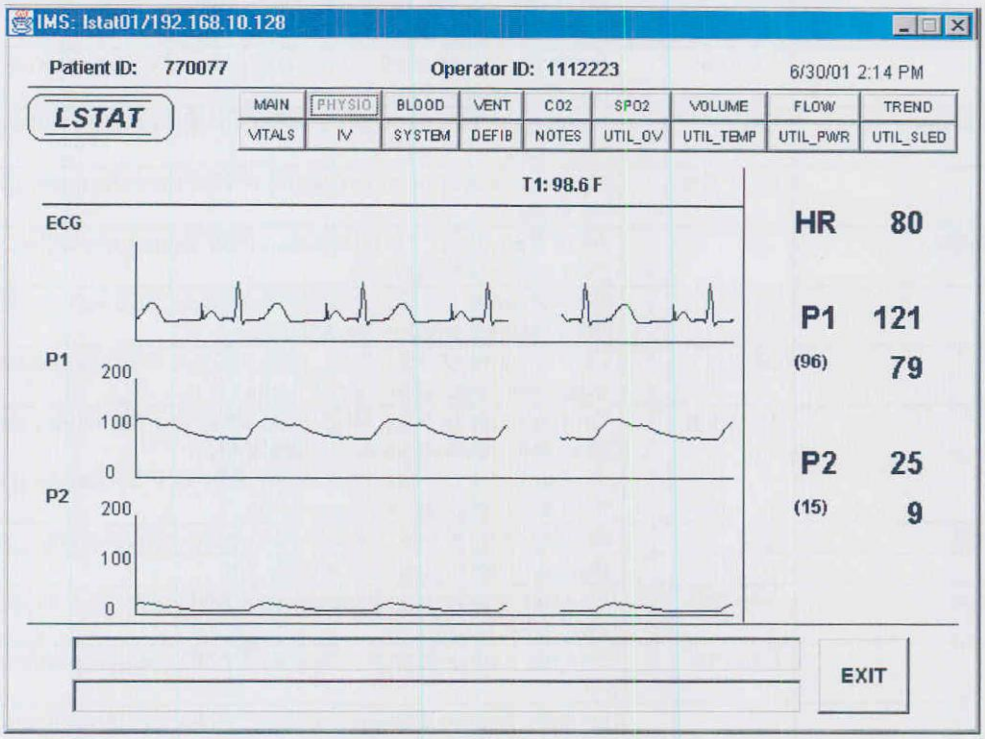
Oxygen

Source: External
Internal Bottle: 739 psi

Figure 11-17. UTIL_OV Screen

11.4.7 Other Screens

Figure 11-18 through 11-29 illustrate the other screens available on the Secondary Display.



IMS: lstat01/192.168.10.128

Patient ID: 770077

Operator ID: 1112223

6/30/01 2:14 PM

T1: 98.6 F

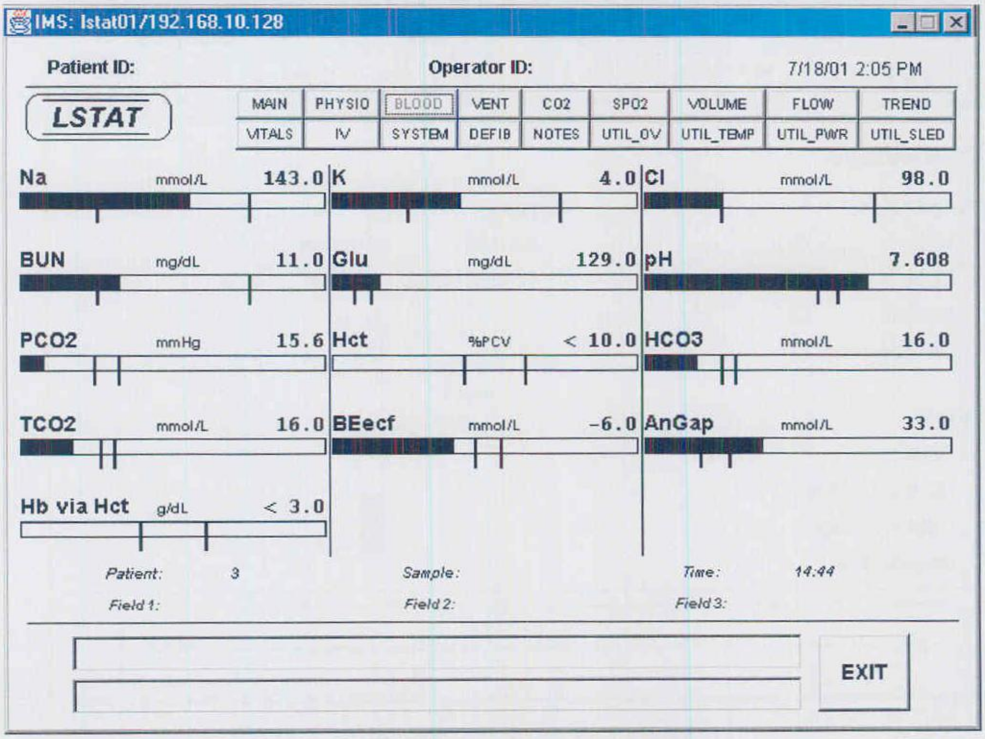
HR 80

P1 121 (96) 79

P2 25 (15) 9

LSTAT
MAIN
PHYSIO
BLOOD
VENT
CO2
SPO2
VOLUME
FLOW
TREND
VITALS
IV
SYSTEM
DEFIB
NOTES
UTIL_OV
UTIL_TEMP
UTIL_PWR
UTIL_SLED
ECG
P1
200
100
0
P2
200
100
0
EXIT

Figure 11-18. PHYSIO Screen



IMS: lstat01/192.168.10.128

Patient ID:

Operator ID:

7/18/01 2:05 PM

Na mmol/L 143.0

K mmol/L 4.0

Cl mmol/L 98.0

BUN mg/dL 11.0

Glu mg/dL 129.0

pH 7.608

PCO2 mmHg 15.6

Hct %PCV < 10.0

HCO3 mmol/L 16.0

TCO2 mmol/L 16.0

BEecf mmol/L -6.0

AnGap mmol/L 33.0

Hb via Hct g/dL < 3.0

Patient: 3

Sample:

Time: 14:44

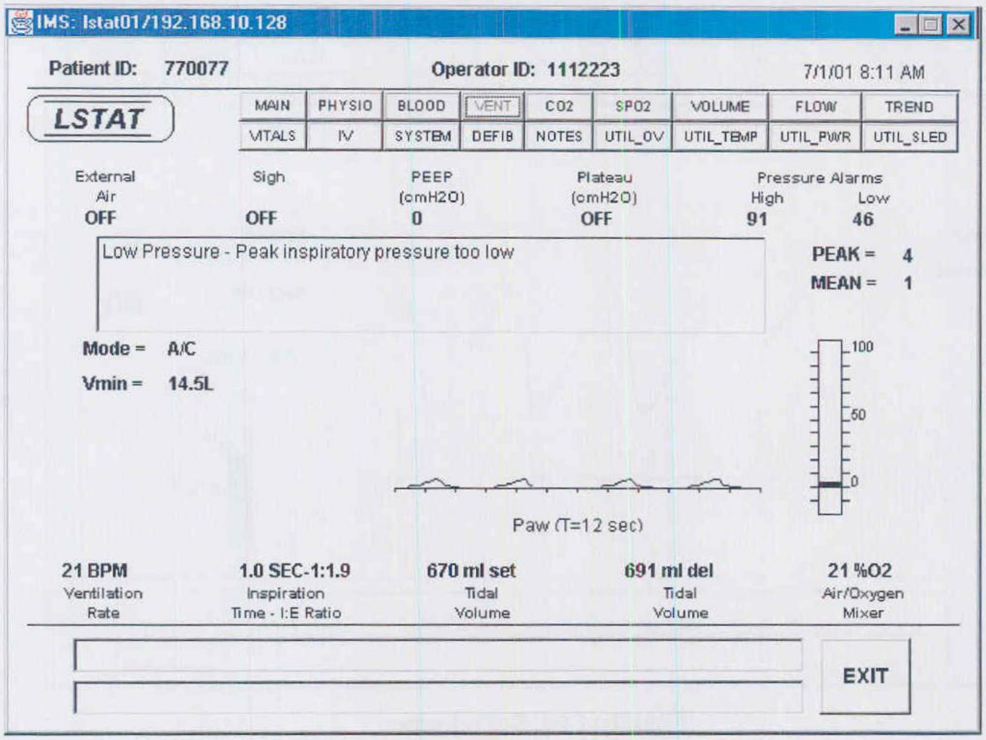
Field 1:

Field 2:

Field 3:

LSTAT
MAIN
PHYSIO
BLOOD
VENT
CO2
SPO2
VOLUME
FLOW
TREND
VITALS
IV
SYSTEM
DEFIB
NOTES
UTIL_OV
UTIL_TEMP
UTIL_PWR
UTIL_SLED
EXIT

Figure 11-19. BLOOD Screen


MAIN
PHYSIO
BLOOD
VENT
CO2
SPO2
VOLUME
FLOW
TREND
VITALS
IV
SYSTEM
DEFIB
NOTES
UTIL_OV
UTIL_TEMP
UTIL_PWR
UTIL_SLED
LSTAT
100
50
0
EXIT

IMS: lstat01/192.168.10.128

Patient ID: 770077

Operator ID: 1112223

7/1/01 8:11 AM

External Air: OFF

Sigh: OFF

PEEP (cmH2O): 0

Plateau (cmH2O): OFF

Pressure Alarms High: 91

Pressure Alarms Low: 46

Low Pressure - Peak inspiratory pressure too low

PEAK = 4

MEAN = 1

Mode = A/C

Vmin = 14.5L

Paw (T=12 sec)

21 BPM Ventilation Rate

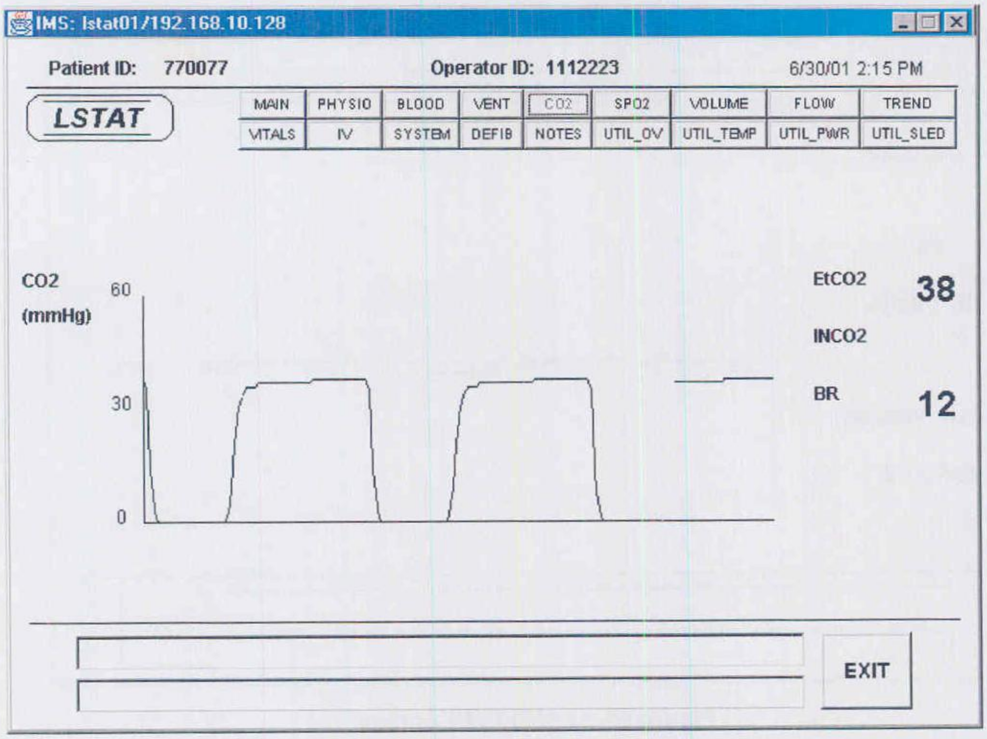
1.0 SEC-1:1.9 Inspiration Time - I:E Ratio

670 ml set Tidal Volume

691 ml del Tidal Volume

21 %O2 Air/Oxygen Mixer

Figure 11-20. VENT Screen


MAIN
PHYSIO
BLOOD
VENT
CO2
SPO2
VOLUME
FLOW
TREND
VITALS
IV
SYSTEM
DEFIB
NOTES
UTIL_OV
UTIL_TEMP
UTIL_PWR
UTIL_SLED
LSTAT
CO2
(mmHg)
60
30
0
EXIT

IMS: lstat01/192.168.10.128

Patient ID: 770077

Operator ID: 1112223

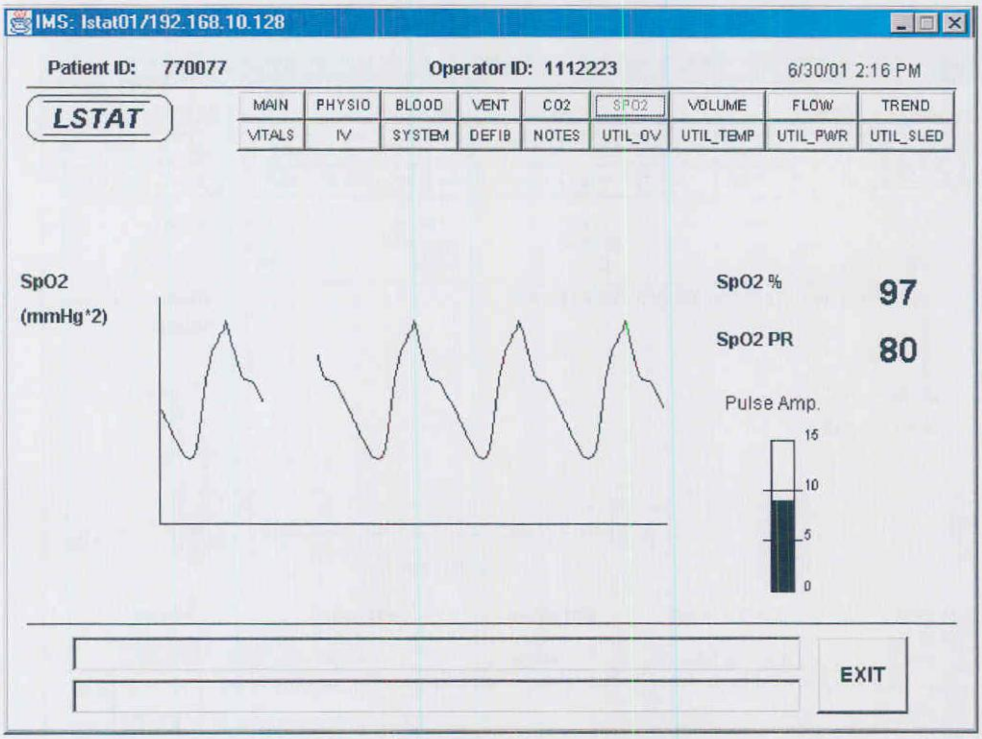
6/30/01 2:15 PM

EtCO2 38

INCO2

BR 12

Figure 11-21. CO_2 Screen



IMS: lstat01/192.168.10.128

Patient ID: 770077

Operator ID: 1112223

6/30/01 2:16 PM

SpO2 (mmHg*2)

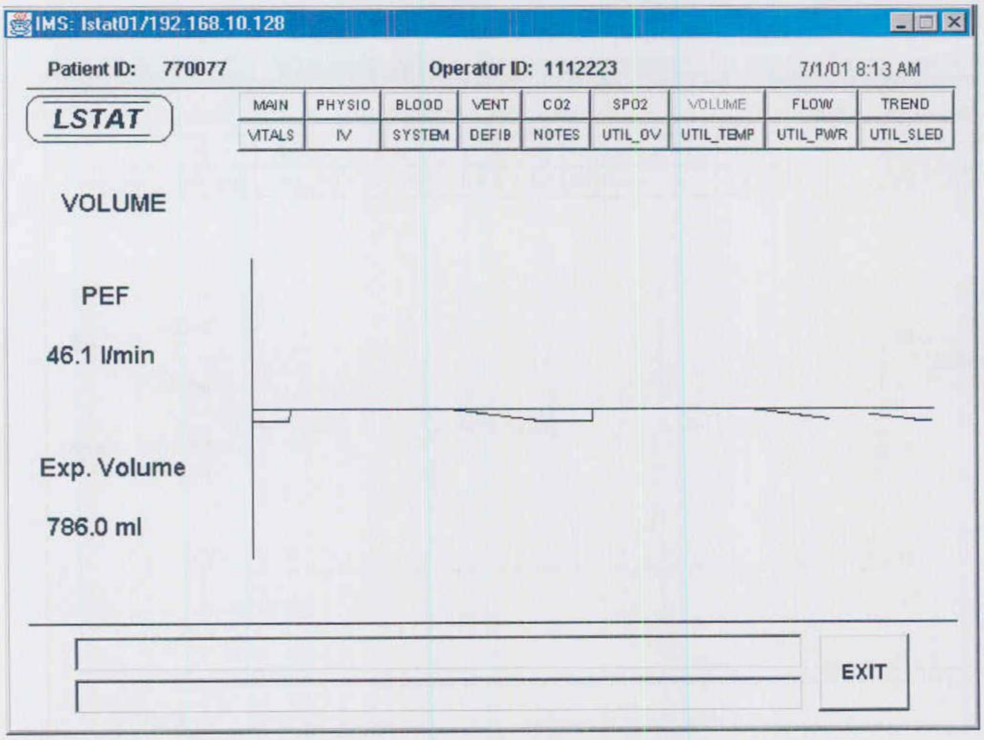
SpO2 % 97

SpO2 PR 80

Pulse Amp.

LSTAT
MAIN
PHYSIO
BLOOD
VENT
CO2
SPO2
VOLUME
FLOW
TREND
VITALS
IV
SYSTEM
DEFIB
NOTES
UTIL_OV
UTIL_TEMP
UTIL_PWR
UTIL_SLED
15
10
5
0
EXIT

Figure 11-22. SpO$_2$ Screen



IMS: lstat01/192.168.10.128

Patient ID: 770077

Operator ID: 1112223

7/1/01 8:13 AM

VOLUME

PEF

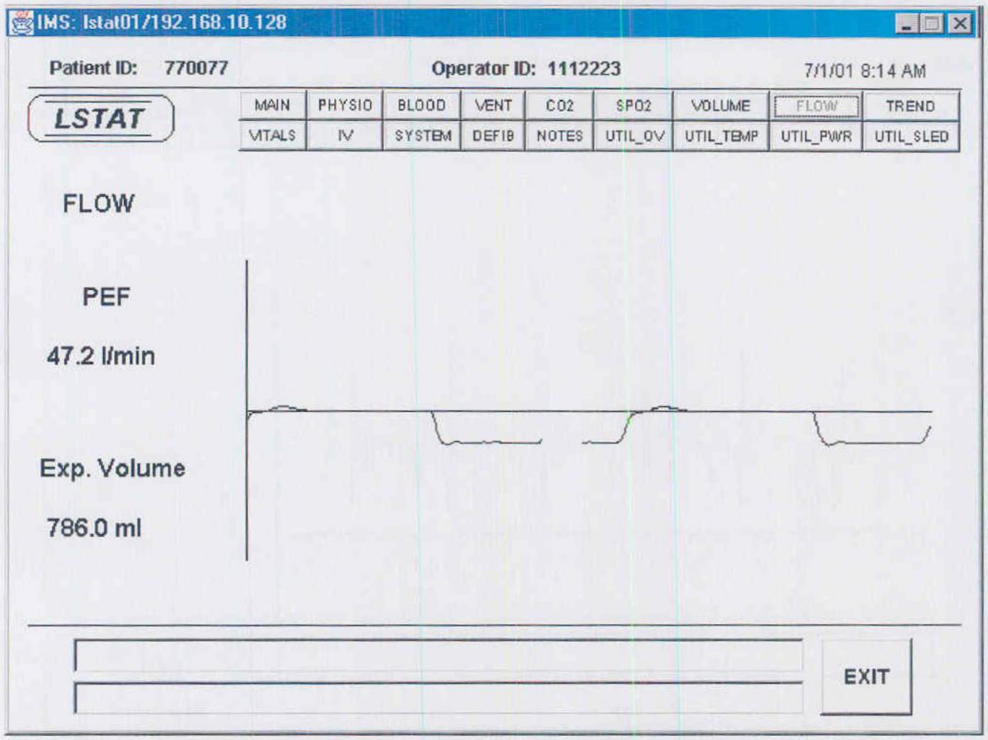
46.1 l/min

Exp. Volume

786.0 ml

LSTAT
MAIN
PHYSIO
BLOOD
VENT
CO2
SPO2
VOLUME
FLOW
TREND
VITALS
IV
SYSTEM
DEFIB
NOTES
UTIL_OV
UTIL_TEMP
UTIL_PWR
UTIL_SLED
EXIT

Figure 11-23. VOLUME Screen


IMS: lstat01/192.168.10.128
LSTAT
MAIN
PHYSIO
BLOOD
VENT
CO2
SPO2
VOLUME
FLOW
TREND
VITALS
IV
SYSTEM
DEFIB
NOTES
UTIL_OV
UTIL_TEMP
UTIL_PWR
UTIL_SLED
EXIT

Patient ID: 770077
Operator ID: 1112223
7/1/01 8:14 AM

FLOW

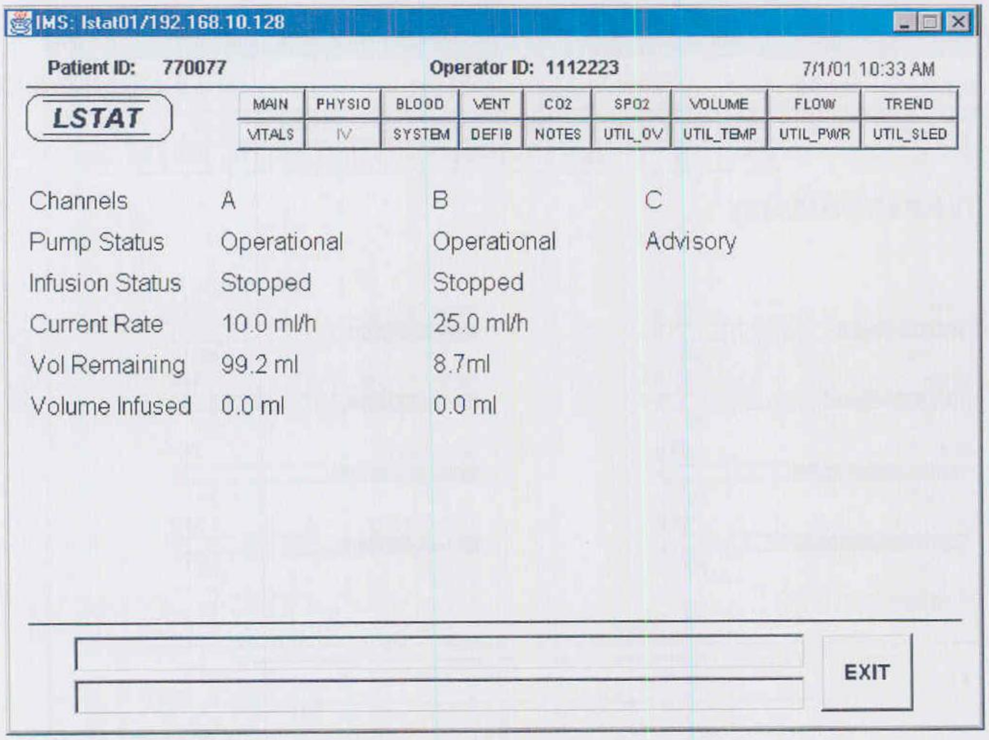
PEF

47.2 l/min

Exp. Volume

786.0 ml

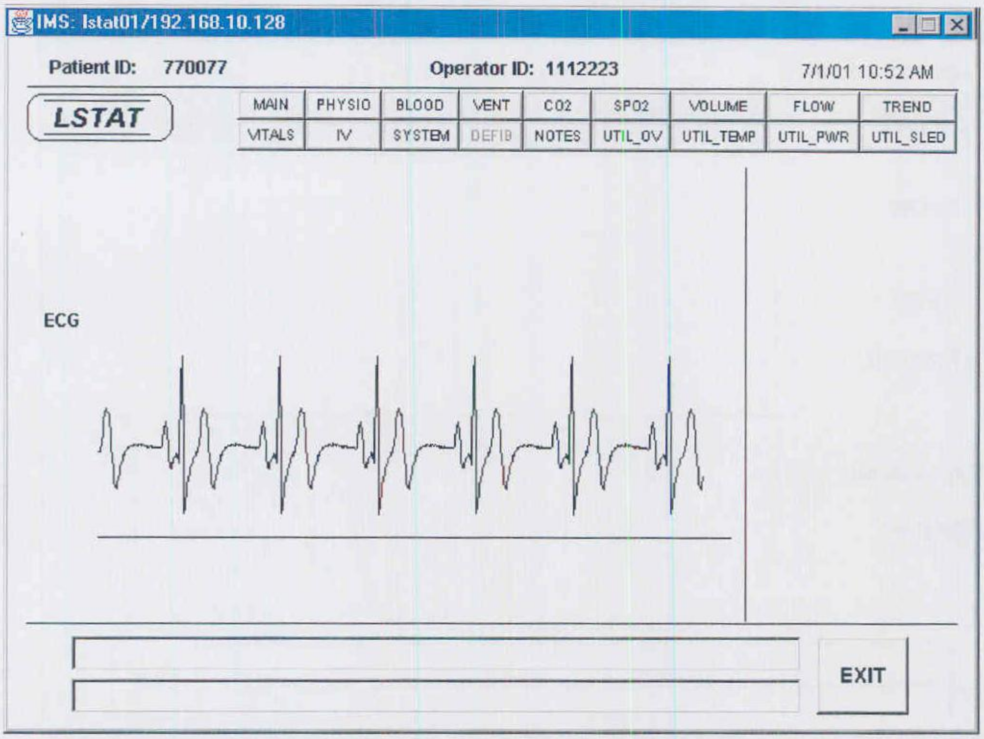
Figure 11-24. FLOW Screen


IMS: lstat01/192.168.10.128
LSTAT
MAIN
PHYSIO
BLOOD
VENT
CO2
SPO2
VOLUME
FLOW
TREND
VITALS
IV
SYSTEM
DEFIB
NOTES
UTIL_OV
UTIL_TEMP
UTIL_PWR
UTIL_SLED
EXIT

Patient ID: 770077
Operator ID: 1112223
7/1/01 10:33 AM

Channels	A	B	C
Pump Status	Operational	Operational	Advisory
Infusion Status	Stopped	Stopped	
Current Rate	10.0 ml/h	25.0 ml/h	
Vol Remaining	99.2 ml	8.7ml	
Volume Infused	0.0 ml	0.0 ml	

Figure 11-25. IV Screen



IMS: lstat01/192.168.10.128

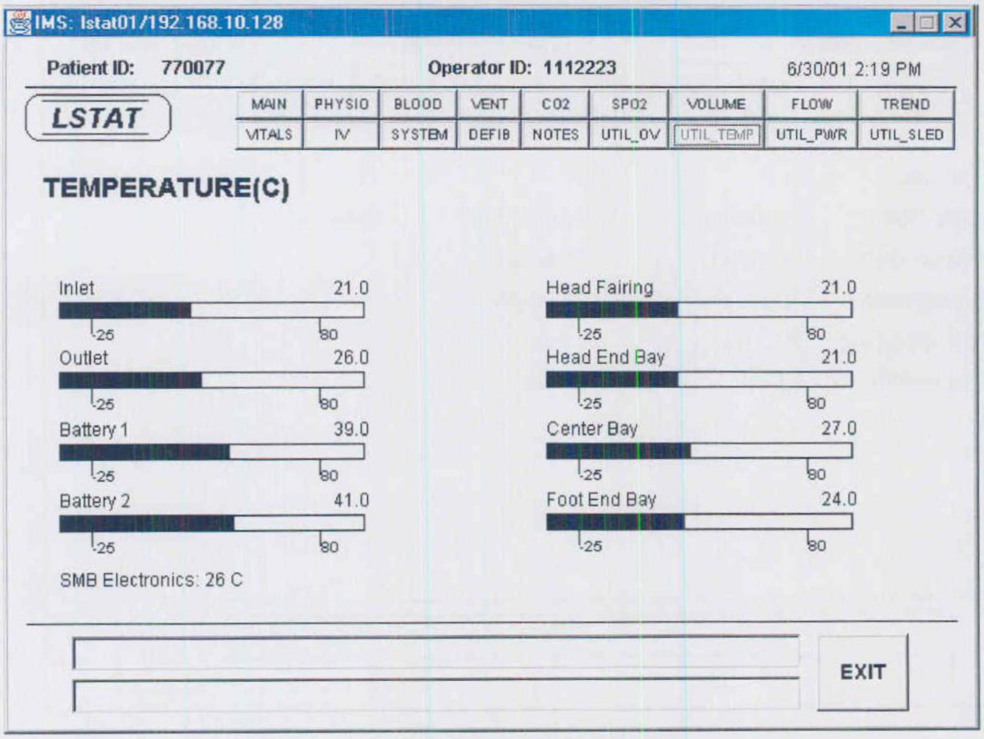
Patient ID: 770077

Operator ID: 1112223

7/1/01 10:52 AM

LSTAT
MAIN
PHYSIO
BLOOD
VENT
CO2
SPO2
VOLUME
FLOW
TREND
VITALS
IV
SYSTEM
DEFIB
NOTES
UTIL_OV
UTIL_TEMP
UTIL_PWR
UTIL_SLED
ECG
EXIT

Figure 11-26. DEFIB Screen



IMS: lstat01/192.168.10.128

Patient ID: 770077

Operator ID: 1112223

6/30/01 2:19 PM

TEMPERATURE(C)

Inlet 21.0

Outlet 26.0

Battery 1 39.0

Battery 2 41.0

Head Fairing 21.0

Head End Bay 21.0

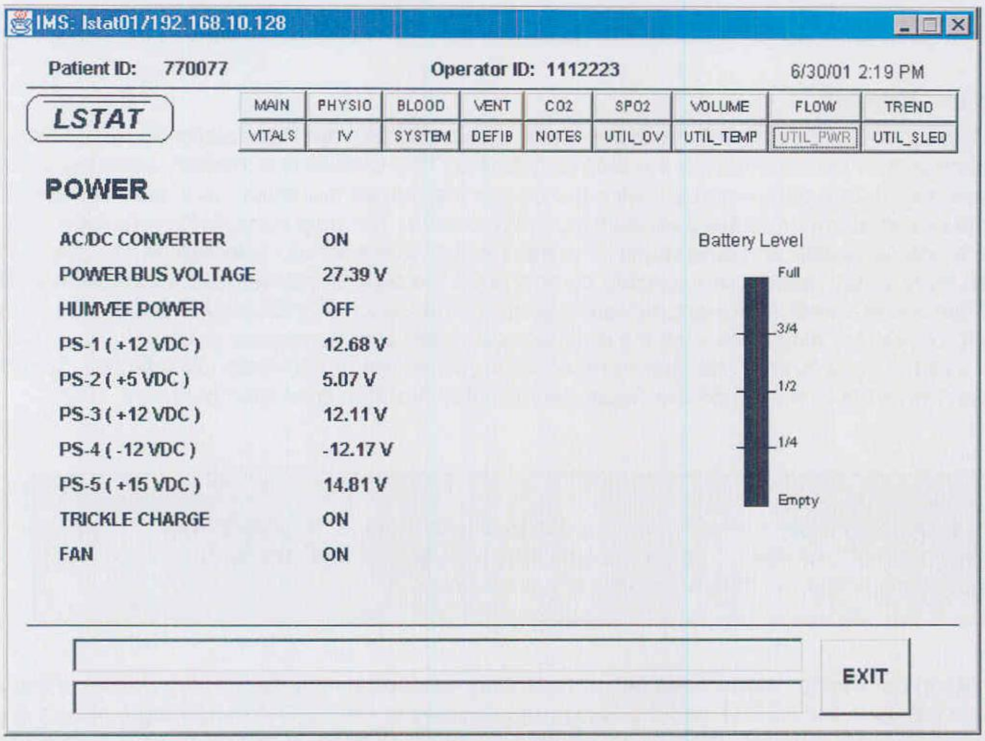
Center Bay 27.0

Foot End Bay 24.0

SMB Electronics: 26 C

LSTAT
MAIN
PHYSIO
BLOOD
VENT
CO2
SPO2
VOLUME
FLOW
TREND
VITALS
IV
SYSTEM
DEFIB
NOTES
UTIL_OV
UTIL_TEMP
UTIL_PWR
UTIL_SLED
-25
80
EXIT

Figure 11-27. UTIL_TEMP Screen

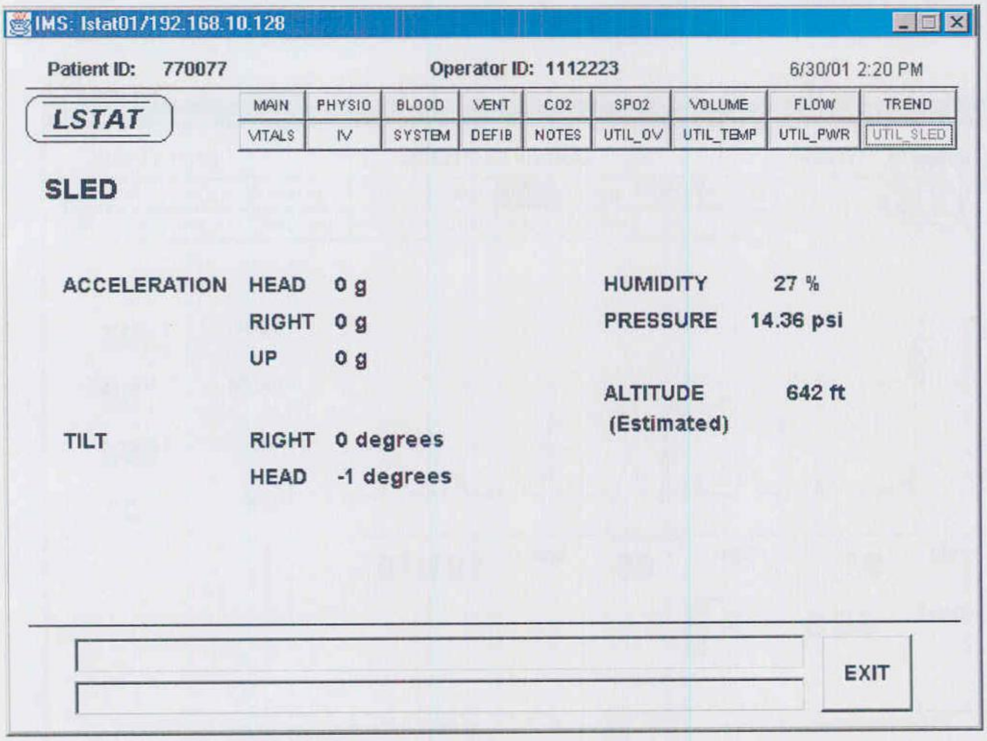

IMS: lstat01/192.168.10.128
LSTAT
MAIN
PHYSIO
BLOOD
VENT
CO2
SPO2
VOLUME
FLOW
TREND
VITALS
IV
SYSTEM
DEFIB
NOTES
UTIL_OV
UTIL_TEMP
UTIL_PWR
UTIL_SLED
Battery Level
Full
3/4
1/2
1/4
Empty
EXIT

Patient ID: 770077
Operator ID: 1112223
6/30/01 2:19 PM

POWER

AC/DC CONVERTER	ON
POWER BUS VOLTAGE	27.39 V
HUMVEE POWER	OFF
PS-1 (+12 VDC)	12.68 V
PS-2 (+5 VDC)	5.07 V
PS-3 (+12 VDC)	12.11 V
PS-4 (-12 VDC)	-12.17 V
PS-5 (+15 VDC)	14.81 V
TRICKLE CHARGE	ON
FAN	ON

Figure 11-28. UTIL_PWR Screen


IMS: lstat01/192.168.10.128
LSTAT
MAIN
PHYSIO
BLOOD
VENT
CO2
SPO2
VOLUME
FLOW
TREND
VITALS
IV
SYSTEM
DEFIB
NOTES
UTIL_OV
UTIL_TEMP
UTIL_PWR
UTIL_SLED
EXIT

Patient ID: 770077
Operator ID: 1112223
6/30/01 2:20 PM

SLED

ACCELERATION HEAD 0 g
RIGHT 0 g
UP 0 g

TILT RIGHT 0 degrees
HEAD -1 degrees

HUMIDITY 27 %
PRESSURE 14.36 psi

ALTITUDE (Estimated) 642 ft

Figure 11-29. UTIL_SLED Screen

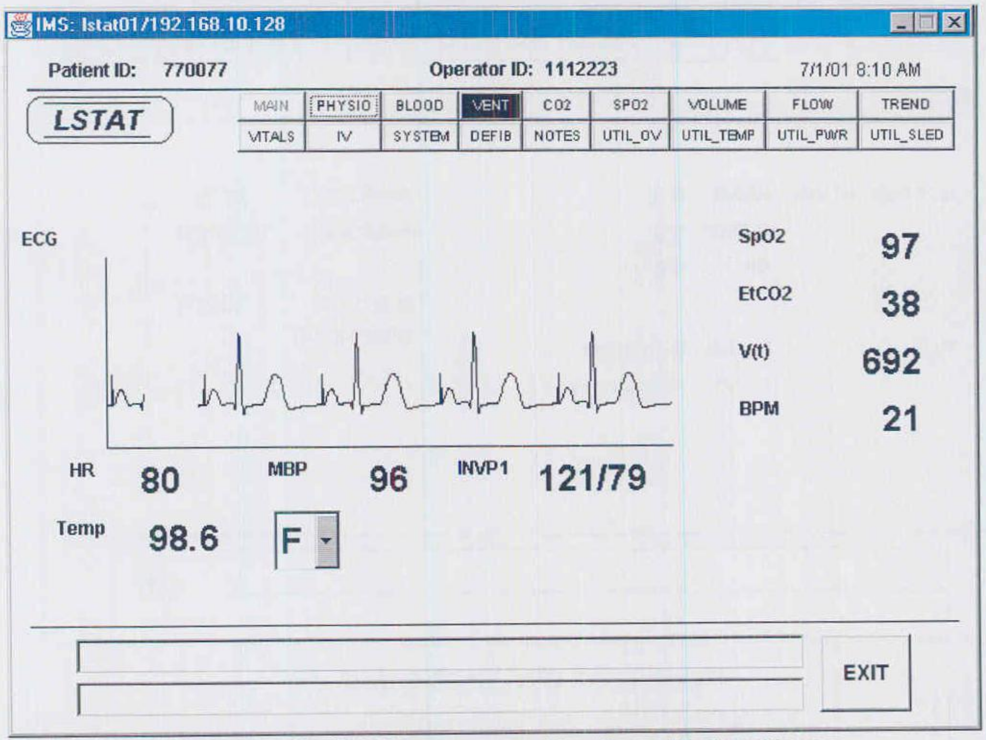
11.5 Secondary Display Warnings, Errors and Alarms

11.5.1 Master Alarms

Secondary Display Master Alarms inform the operator that an LSTAT device is alarming by flashing the screen selection button associated with the alarming device. This feature is especially valuable when the LSTAT is operating in an environment in which the device alarms are inaudible, such as in a helicopter. The visual cue draws attention to the Secondary Display screen. The operator can then quickly identify which device is alarming without being required to have the device's screen selected on the Secondary Display nor to have visual contact (nor audible contact) with the alarming device's primary display. Then the operator can either switch to the appropriate screen on the Secondary Display or go directly to the alarming device's primary display to view the detailed alarm and take necessary action. Figure 11-30 illustrates an example of a "VENT" master alarm occurring while the MAIN screen is selected. The details of the alarm on the "VENT" screen on the Secondary Display are then illustrated in Figure 11-31.

> NOTE:
> Not all devices have a master alarm associated with them (see Table 11-5). Therefore the user must be aware of which devices do not and take appropriate precautions when visual or audio disturbances arise.

If for some reason the Master Alarm message is not being received by the Secondary Display either due to a disconnect between the LSTAT and the Secondary Display or the LSTAT is running a pre-V1.3 version of the embedded software, the LSTAT graphic will begin to flash (see Figure 11-32). In addition, one of two warning messages will be displayed in Message Field 1: "Master alarms are unavailable. Check communication link" or "Master alarms are unavailable. Incompatible embedded software version." Depending on the conditions of the error.

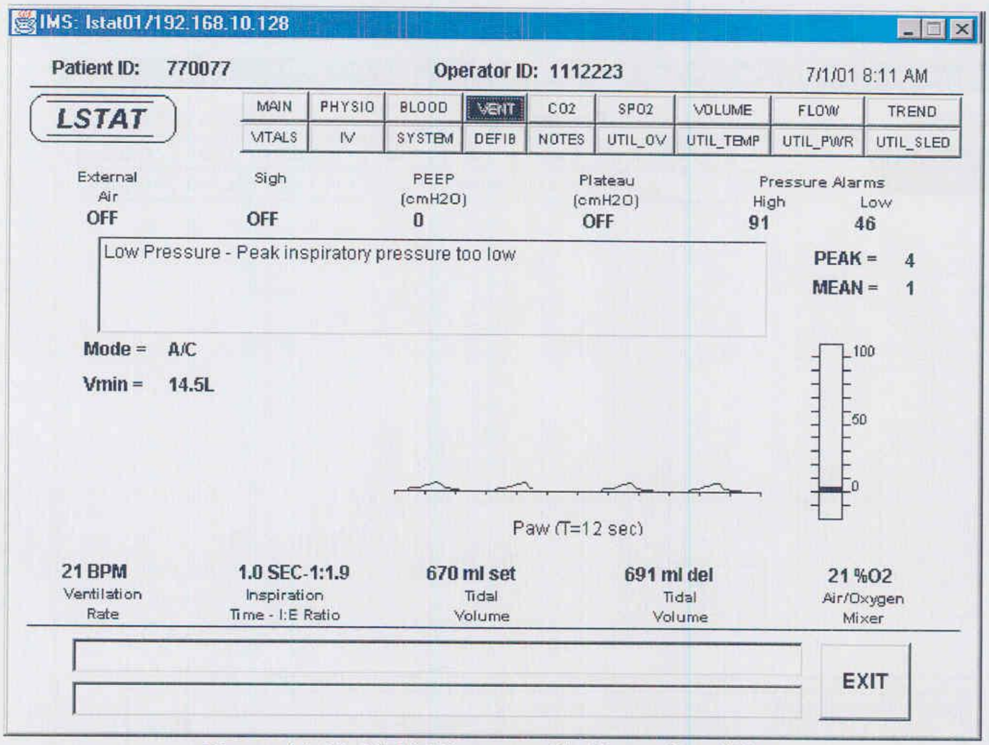


Patient ID: 770077
Operator ID: 1112223
7/1/01 8:10 AM

SpO2 97
EtCO2 38
V(t) 692
BPM 21

HR 80
MBP 96
INVP1 121/79
Temp 98.6 F

Figure 11-30. MAIN Screen with Ventilator Master Alarm



IMS: lstat01/192.168.10.128

Patient ID: 770077

Operator ID: 1112223

7/1/01 8:11 AM

External Air: OFF

Sigh: OFF

PEEP (cmH2O): 0

Plateau (cmH2O): OFF

Pressure Alarms High: 91

Pressure Alarms Low: 46

Low Pressure - Peak inspiratory pressure too low

PEAK = 4

MEAN = 1

Mode = A/C

Vmin = 14.5L

21 BPM Ventilation Rate

1.0 SEC-1:1.9 Inspiration Time - I:E Ratio

670 ml set Tidal Volume

691 ml del Tidal Volume

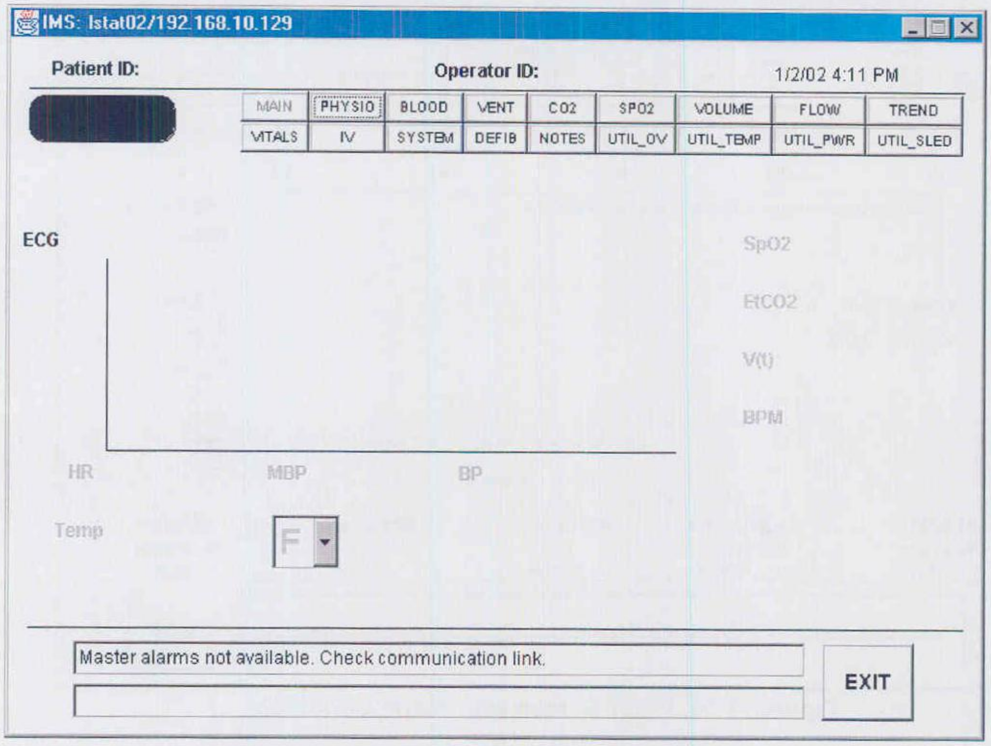
21 %O2 Air/Oxygen Mixer

Figure 11-31. VENT Screen with Alarm Condition

Table 11-5 identifies the Secondary Display buttons that are programmed as master alarms and the conditions that will activate the alarm.

Table 11-5. Secondary Display Master Alarm Buttons

Screen Button	Alarm Condition Description
MAIN, PHYSIO, CO_2, SpO_2	These four buttons flash simultaneously when there is an alarm condition on the Physiological Monitor.
VENT	The "VENT" button flashes whenever there is an alarm condition on the Ventilator.
IV	The "IV" button flashes whenever there is an alarm condition on the IVAC unit.
DEFIB	The "DEFIB" button flashes when the Defibrillator is in ready to rescue mode. The "DEFIB" button flashes at approximately the same time that the Defibrillator announces the audio message: "Stand clear, push flashing button to rescue".
UTIL_OV	The "UTIL_OV" button flashes when the internal oxygen level is less than 500 psi.
UTIL_PWR	The "UTIL_PWR" button flashes when the battery level "low" discrete is set.


IMS: lstat02/192.168.10.129
Patient ID:
Operator ID:
1/2/02 4:11 PM
MAIN
PHYSIO
BLOOD
VENT
CO2
SPO2
VOLUME
FLOW
TREND
VITALS
IV
SYSTEM
DEFIB
NOTES
UTIL_OV
UTIL_TEMP
UTIL_PWR
UTIL_SLED
ECG
SpO2
EtCO2
V(t)
BPM
HR
MBP
BP
Temp
F
EXIT

Master alarms not available. Check communication link.

Figure 11-32. No Master Alarms Condition

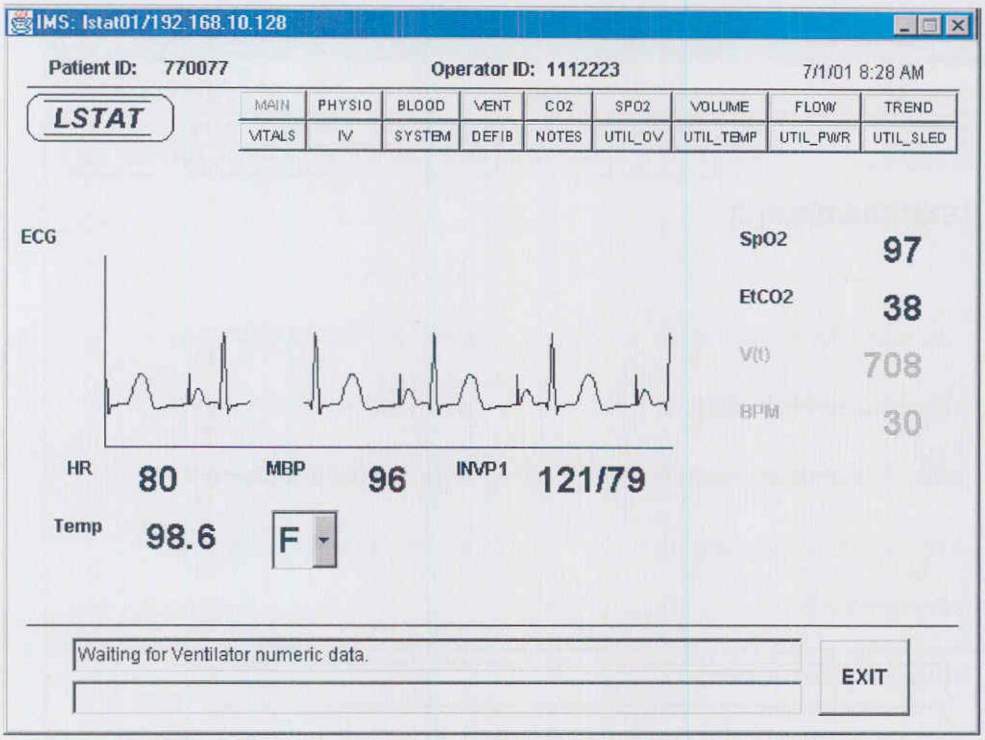
11.5.2 Secondary Display System Messages and Invalid Data Indications

The Secondary Display software detects packet errors such as incorrect packet size, out of sequence or missing data, etc., as well as the non-responsiveness of the LSTAT system (i.e. not receiving data as expected). The software informs the operator of possible lost or corrupt data by graying out the invalid data and/or displaying an informative message in Message Field 1 at the bottom of the screen. If more than one error occurs simultaneously, an error list is created and Message Field 1 will cycle through the list, displaying each message for approximately 1 second. Since some errors only occur for a second or two, it is possible that some error messages will be deleted from list before they have been displayed. Thus, the operator will only be informed of an error condition by the graying out of the affected data.

Typical errors as handled by the Secondary Display software are listed in Table 11-6 and examples are illustrated in Figure 11-33 through Figure 11-35. Appendix L lists all possible messages that can be displayed in Message Field 1.

Table 11-6. General Secondary Display Errors

Description	**Example**	**Formats in which error occurs.**
Device(s) or LSTAT not responding.	Figure 11-33	All
Missed packets due to interruption in communication with the LSTAT or a particular medical device.	Figure 11-34	All
Out of date data.	Figure 11-14	TREND, VITALS
Data out of range.	Figure 11-35	UTIL_TEMP, UTIL_PWR

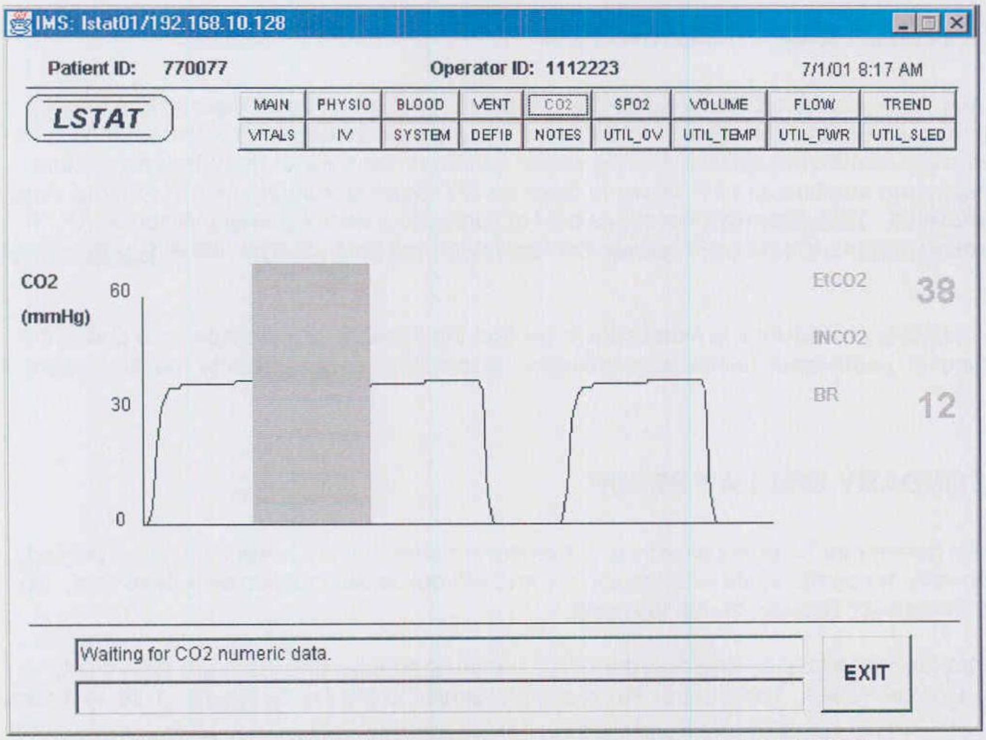

IMS: lstat01/192.168.10.128

Patient ID: 770077 Operator ID: 1112223 7/1/01 8:28 AM

Waiting for Ventilator numeric data.

LSTAT
MAIN
PHYSIO
BLOOD
VENT
CO2
SPO2
VOLUME
FLOW
TREND
VITALS
IV
SYSTEM
DEFIB
NOTES
UTIL_OV
UTIL_TEMP
UTIL_PWR
UTIL_SLED
ECG
SpO2 97
EtCO2 38
V(t) 708
BPM 30
HR 80
MBP 96
INVP1 121/79
Temp 98.6
F
EXIT

Figure 11-33. Example of Secondary Display not receiving Ventilator Data.

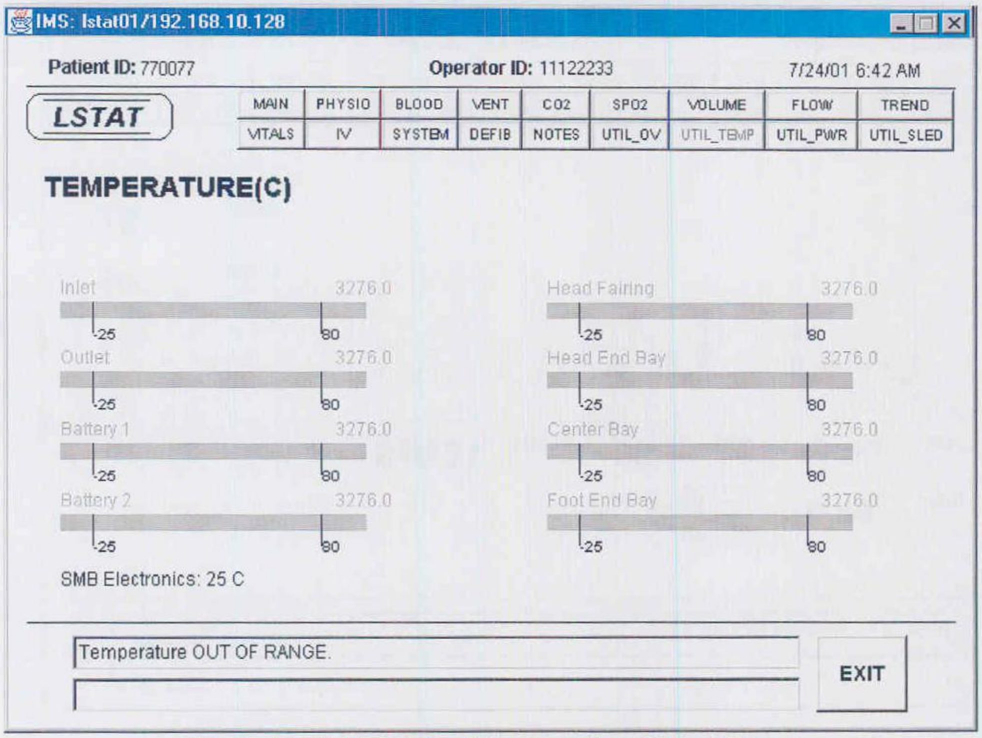

IMS: lstat01/192.168.10.128

Patient ID: 770077 Operator ID: 1112223 7/1/01 8:17 AM

Waiting for CO2 numeric data.

LSTAT
MAIN
PHYSIO
BLOOD
VENT
CO2
SPO2
VOLUME
FLOW
TREND
VITALS
IV
SYSTEM
DEFIB
NOTES
UTIL_OV
UTIL_TEMP
UTIL_PWR
UTIL_SLED
CO2 (mmHg)
60
30
0
EtCO2 38
INCO2
BR 12
EXIT

Figure 11-34. Examples of Missed Waveform and Numeric Data



Patient ID: 770077 **Operator ID:** 11122233 7/24/01 6:42 AM

TEMPERATURE(C)

Inlet 3276.0
Outlet 3276.0
Battery 1 3276.0
Battery 2 3276.0
Head Fairing 3276.0
Head End Bay 3276.0
Center Bay 3276.0
Foot End Bay 3276.0
SMB Electronics: 25 C

Temperature OUT OF RANGE.

Figure 11-35. Example of Temperature Out of Range

11.6 NETWORK CONFIGURATION

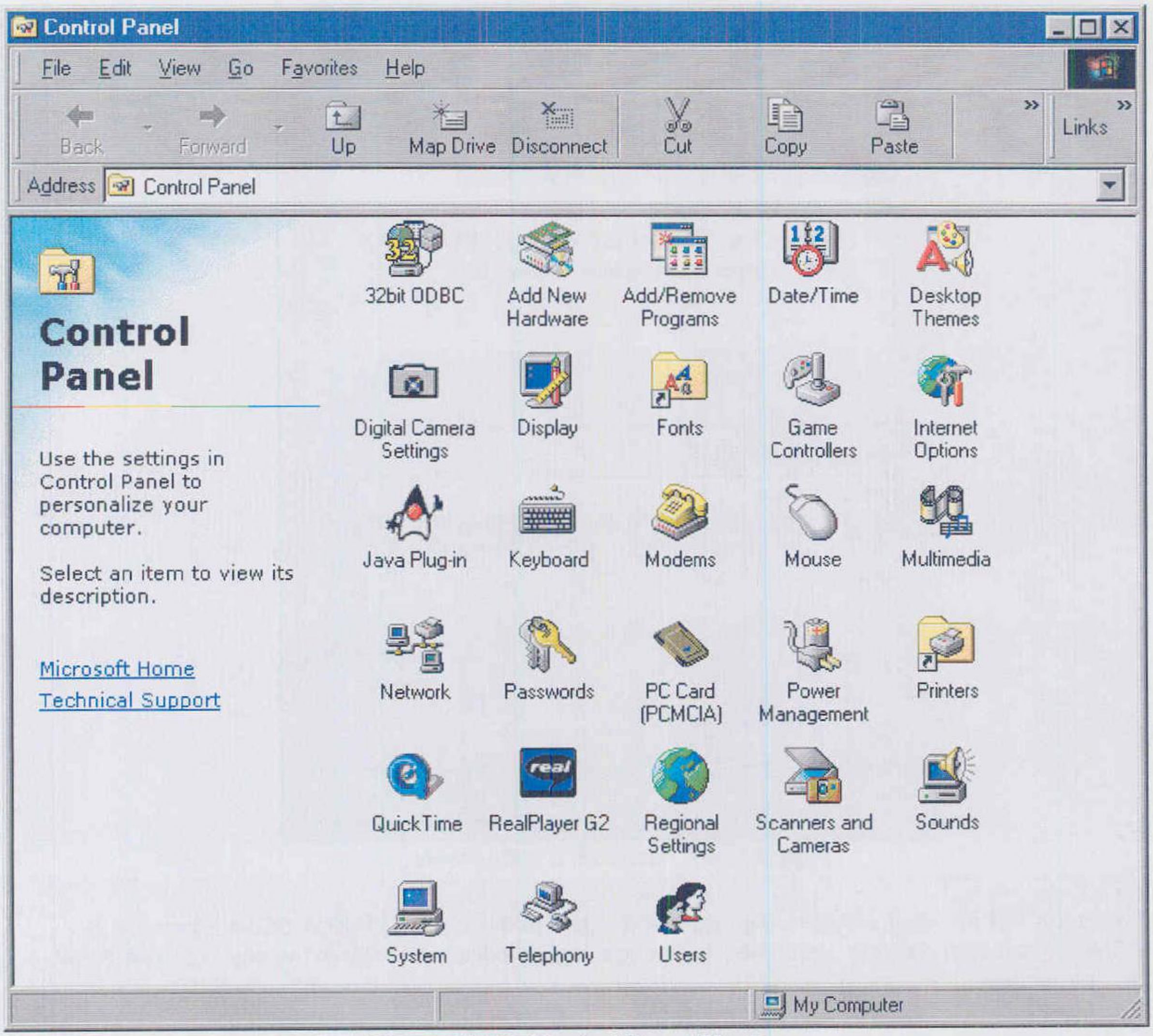
The LSTAT and the Secondary Display Local Area Network (LAN) must be configured in a manner that they may communicate with each other. In addition, if it is planned to download files from the LSTAT, an LSTAT server must also be configured. The file server can be running either the Windows or Linux operating system and must be an FTP server or have an FTP daemon running on it in order to receive the downloaded files. This document describes how to configure a server running Windows XP. If another operating system is to be used, please contact Integrated Medical Systems at support@lstat.com for help.

Prior to beginning this procedure it is necessary to contact the network administrator and obtain the Internet Protocol (IP) addresses to configure the systems to as well as the gateway machine address and net mask.

11.6.1 SECONDARY DISPLAY SETUP

Configuring the Secondary Display correctly is extremely important for if it is not configured properly, the unit will not be able to communicate with the LSTAT and will not be able to display patient data. To configure the Secondary Display, do the following.

1. Bring up the Control Panel by pressing the 'Start' button, then selecting 'Settings' and, finally, selecting 'Control Panel'. The Control Panel display, similar to the one in Figure 11-36, is displayed.

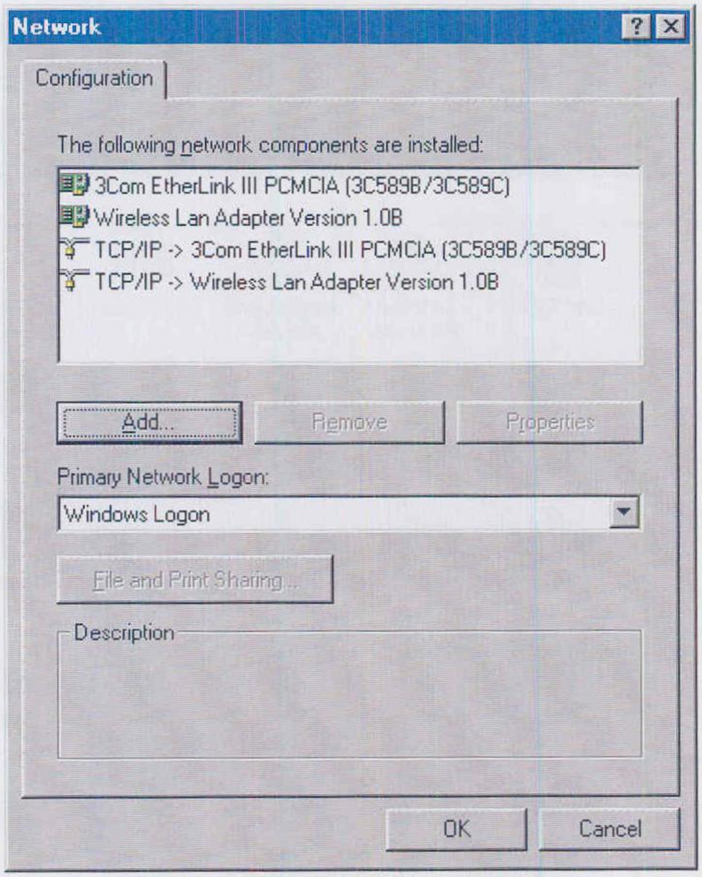

Control Panel
File Edit View Go Favorites Help
Back
Forward
Up
Map Drive
Disconnect
Cut
Copy
Paste
Links
Address
Control Panel
Control Panel
32bit ODBC
Add New Hardware
Add/Remove Programs
Date/Time
Desktop Themes
Digital Camera Settings
Display
Fonts
Game Controllers
Internet Options
Java Plug-in
Keyboard
Modems
Mouse
Multimedia
Network
Passwords
PC Card (PCMCIA)
Power Management
Printers
QuickTime
RealPlayer G2
Regional Settings
Scanners and Cameras
Sounds
System
Telephony
Users
Microsoft Home
Technical Support
My Computer

Use the settings in Control Panel to personalize your computer.

Select an item to view its description.

Figure 11-36. Control Panel Display

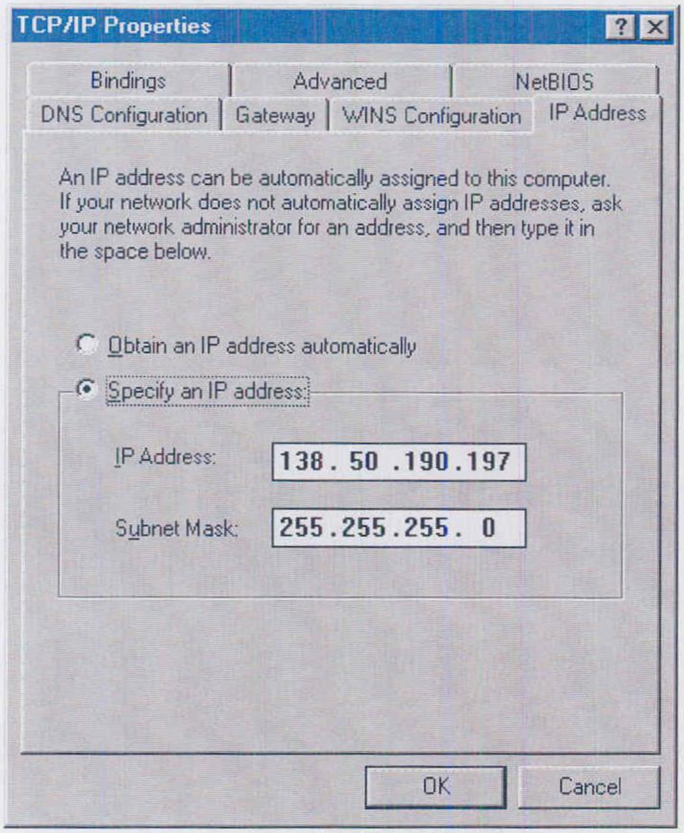
2. Find and double-click the 'Network' icon to bring up the Network configuration display similar to the one shown in Figure 11-37.



Network
Configuration
The following network components are installed:
3Com EtherLink III PCMCIA (3C589B/3C589C)
Wireless Lan Adapter Version 1.0B
TCP/IP -> 3Com EtherLink III PCMCIA (3C589B/3C589C)
TCP/IP -> Wireless Lan Adapter Version 1.0B
Add...
Remove
Properties
Primary Network Logon:
Windows Logon
File and Print Sharing...
Description
OK
Cancel

Figure 11-37. Network Configuration

3. Select the TCP/IP which points to the Ethernet adaptor, in this case 'TCP/IP -> 3Com EtherLink III PCMCIA' and then click the 'Properties' button to bring up a display similar to the one in Figure 11-38.


TCP/IP Properties

An IP address can be automatically assigned to this computer. If your network does not automatically assign IP addresses, ask your network administrator for an address, and then type it in the space below.

○ Obtain an IP address automatically

● Specify an IP address:

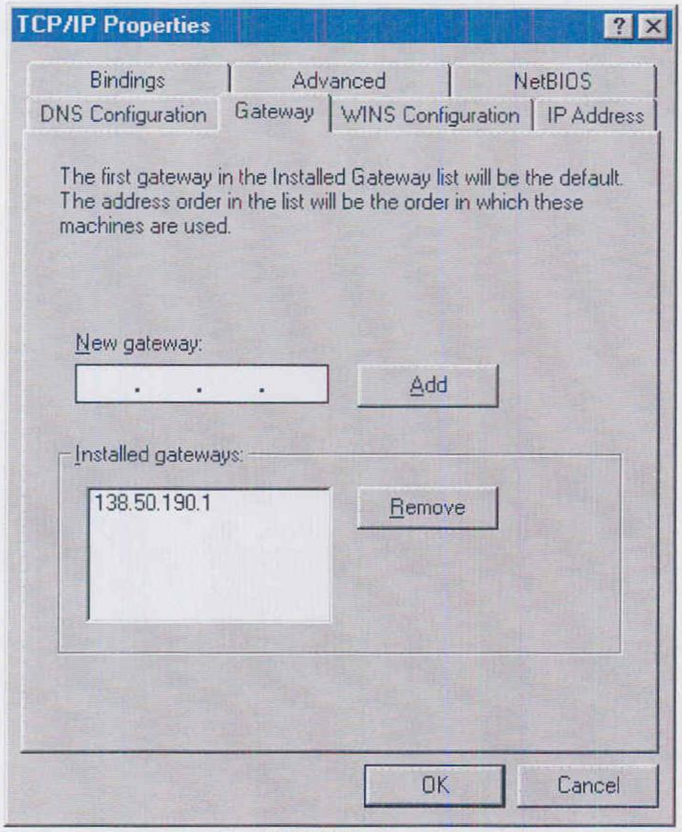
IP Address: 138 . 50 .190 .197

Subnet Mask: 255 .255 .255 . 0

? ×
Bindings
Advanced
NetBIOS
DNS Configuration
Gateway
WINS Configuration
IP Address
OK
Cancel

Figure 11-38 TCP/IP Properties

4. Make sure 'Specify an IP address' radio button is selected, then input the new IP address provided by the systems administrator. The Subnet Mask is normally 255.255.255.0, but make sure that the system administrator provides this as well. When you have finished inputting and verifying the IP Address and Subnet Mask, click the 'Gateway' tab near the top of the display to get the display shown in Figure 11-39.


TCP/IP Properties
Bindings
Advanced
NetBIOS
DNS Configuration
Gateway
WINS Configuration
IP Address
Add
Remove
OK
Cancel

The first gateway in the Installed Gateway list will be the default. The address order in the list will be the order in which these machines are used.

New gateway: . . .

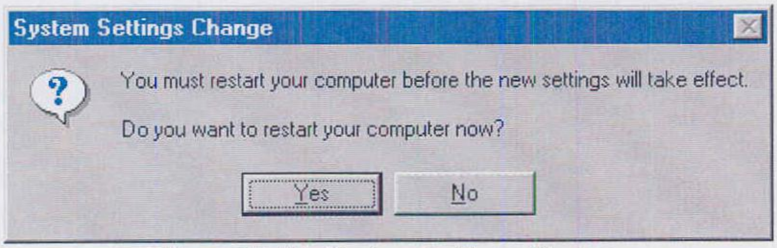
Installed gateways: 138.50.190.1

Figure 11-39. TCP/IP Properties - Gateway

5. If there are any installed gateways, select them and then click the 'Remove' button. Type in your gateway address in the 'New gateway' field and then click the 'Add' button. Your gateway will then appear in the installed gateways area.

6. Click the 'OK; button to confirm all the network changes you have made. This will take you back to the Network Configuration menu in Figure 11-37.

7. Click the 'OK' button on the Network Configuration menu. Windows will now ask you if you would like to restart as shown in Figure 11-40.


System Settings Change
Yes
No

You must restart your computer before the new settings will take effect.

Do you want to restart your computer now?

Figure 11-40. System Settings Change

8. Click the 'Yes' button to reboot Windows using the new network configuration.

11.6.2 LSTAT SET-UP

The LSTAT Internet Protocol (IP) address can only be set when the LSTAT is in maintenance mode.

1. Press the *CMD* and *RST* button on the Indicator panel to get into the MAINTENANCE mode on the Data Entry and Display Panel.

2. Press and hold the *LAMP* button on the Indicator Panel until the message, "MAINTENANCE MODE SET TIME" appears on the Data Entry and Display Panel display.
3. Observe the MAINT light on the Indicator Panel turns on yellow.
4. Press *FWD* until the Data Entry and Display Panel display reads "MAINTENANCE MODE – NEW IP ADDRESS.
5. Press *ENT* on the Data Entry keypad.
6. Press the number keys on the Data Entry keypad to enter the new IP address. The cursor automatically advances past the decimal points.
7. Press the *ENT* button to set the IP address.
8. Press *FWD* once to see the message "MAINTENANCE MODE – SET NETMASK" appear.
9. Press *ENT* on the Data Entry keypad.
10. Press the number keys on the Data Entry keypad to enter the new net mask. The cursor automatically advances past the decimal points.
11. Press the *ENT* button to set the net mask.
12. Press *FWD* once to see the message "MAINTENANCE MODE – SET IP GATEWAY" appear.
13. Press *ENT* on the Data Entry keypad.
14. Press the number keys on the Data Entry keypad to enter the new IP gateway. The cursor automatically advances past the decimal points.
15. Press the *ENT* button to set the IP gateway.
16. Press *FWD* once to see the message "MAINTENANCE MODE ***GO OPERATIONAL***".
17. Press *ENT* on the Data Entry keypad and note the Data Entry and Display Panel display reads "***GO OPERATIONAL*** PRESS ENT TO OPERATE".
18. Press the *ENT* button twice to restart the DDLS.
19. Observe the MAINT light on the Indicator Panel is off.
20. Observe the STATUS light on the Indicator Panel is green.

11.6.3 SERVER SET-UP

The LSTAT server comes as a pre-configured laptop running the Windows operating system. Once booted up, the server will automatically look for and download files from the LSTAT it is configured for at power-up and then once every 15 minutes thereafter.. If the LSTAT is to be reassigned an IP address, then follow the Windows on-line help instructions for "Configure TCP/IP for static addressing" on how to reassign the IP address of the server and software. You will need to get the static IP address, net mask and gateway IP from your network administrator before starting.

11.7 DOWNLOADING

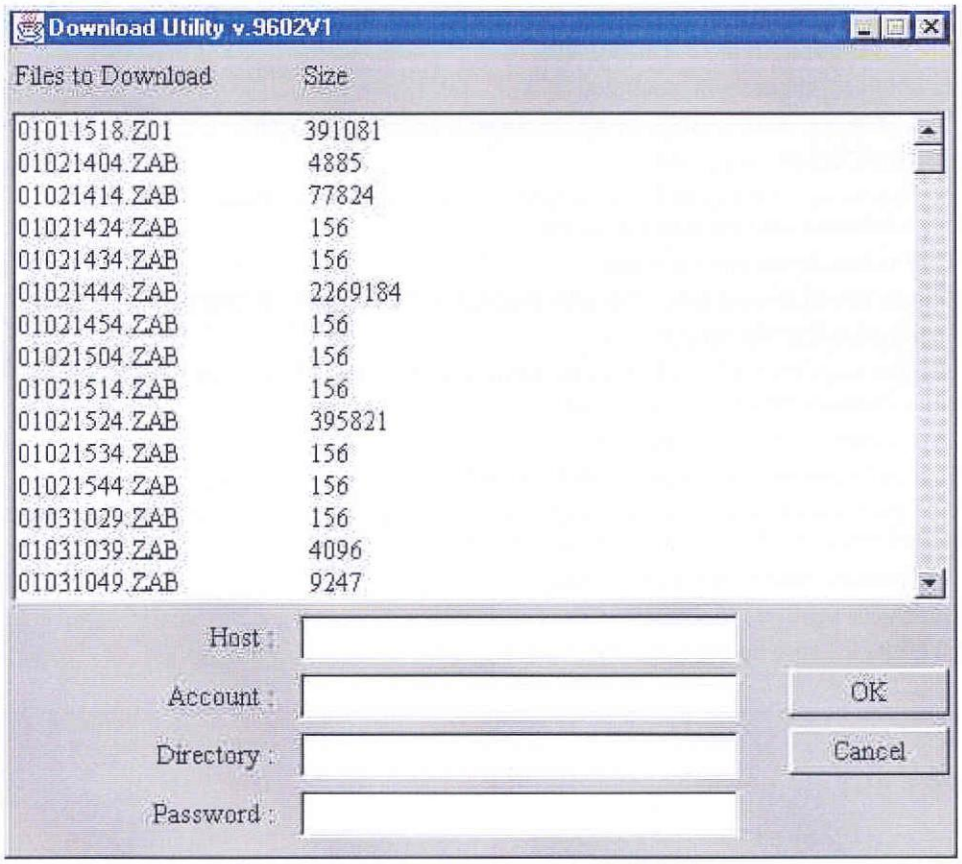
11.7.1 Downloading Patient Files

Patient files are downloaded onto a server using a java program called FTPUtility. Before running this program, you may need to run the utility program FTPRoute. This selects the LSTAT from which files will be downloaded. Once FTPUtility is started, you will get a display similar to the one in Figure 11-41. This screen lists the patient files available for download and their file size (in bytes). Select the file(s) you would like to download with the mouse, and then fill out the required transfer information at the bottom of the screen.

1. Host: This is the name (or IP address) of the computer to transfer the files to.

Note: The computer to transfer files to must be a server or have an Ftp daemon running on it in order to receive file transfers.

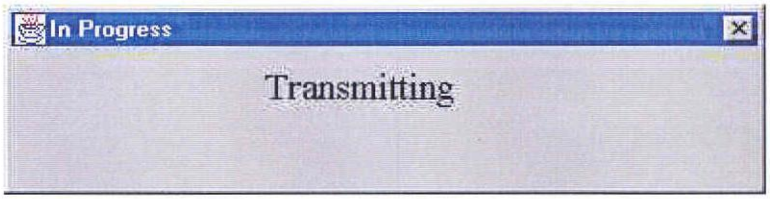
2. Account: Enter the login username on the destination machine.
3. Directory: Enter the destination directory for the patient files.
4. Password: Enter the password for the user account on the destination machine.



Files to Download	Size
01011518.Z01	391081
01021404.ZAB	4885
01021414.ZAB	77824
01021424.ZAB	156
01021434.ZAB	156
01021444.ZAB	2269184
01021454.ZAB	156
01021504.ZAB	156
01021514.ZAB	156
01021524.ZAB	395821
01021534.ZAB	156
01021544.ZAB	156
01031029.ZAB	156
01031039.ZAB	4096
01031049.ZAB	9247

Figure 11-41 FTPUtility download screen

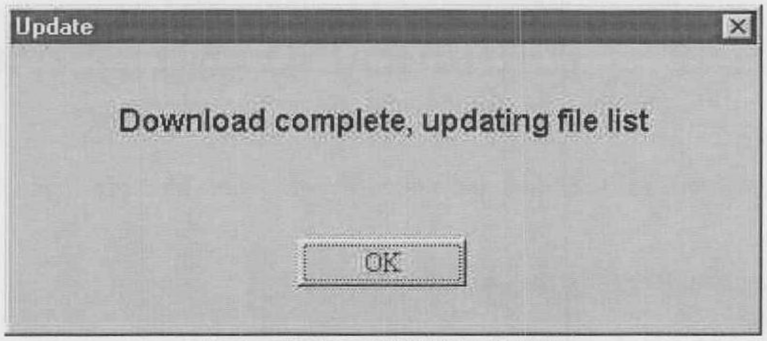
5. Once all the information is entered, press the 'OK' button to begin transferring the selected files. (Note: the selected files will be removed from the original LSTAT system disk.) While the LSTAT is transferring the files to the destination computer you will see the display in Figure 11-42.



Transmitting

Figure 11-42. FTPUtility In Progress

6. Once the transfer is complete, you will see the following screen shot (Figure 11-43). Click the 'OK' button to acknowledge and to update the file list.



Download complete, updating file list

Figure 11-43. FTPUtility Update

7. When finished downloading patient files. Press the "Cancel' button on the main FTPUtility download screen shown in Figure 11-41.

CHAPTER 12 TURNAROUND AND SERVICING

12.1 Equipment

The following equipment is required to perform maintenance, equipment setup and operational checkout of the LSTAT.

- Portable Clinical Analyzer Electronic Simulator, P/N 130200
- Screwdriver, Phillips #2
- Screwdriver, flat tip #2

CAUTION

- Do not immerse the LSTAT in water or direct a stream of water on the structure. The LSTAT is not a watertight unit. Damage to electrical/electronic components may result. Hand clean only.
- Quaternary Germicidal Disinfectants, used as directed, and/or Chlorine Bleach products, typically 5.25% Sodium Hypochlorite in dilution's ranging between 1 part bleach to 100 parts water, and 2 parts bleach to 100 parts water are not considered mild detrergents. These products are corrosive in nature and may cause damage to the pads if used improperly. If these types of products are used to clean patient pads, measures must be taken to insure the pads are rinsed with clean water and thoroughly dried following cleaning. Failure to properly rinse and dry the pads will leave corrosive residue on the surface of the pads. Failure to follow this note may cause premature wear out of the pads.

- Adjustable wrench
- Open End wrench, 1 1/8"
- Nut Driver
- External power source
- Flashlight
- Disinfectant supplies, Leak Detection Fluid
- 12" non-sterile hose.
- Flat wrench, 15°, 1 1/8"
- Oxygen Wrenches (supplied in accessory bag)

Refer to the appropriate sections of Appendix D when replacement accessories are required.

12.2 Cleaning

12.2.1 LSTAT Structure

1. Hand wash patient pad surfaces (both sides) with warm water and mild detergent. Dry thoroughly.
2. Clean the head fairing, foot, sides, compartment covers, litter foot wells and bottom of the structure.
3. Allow to air dry.

12.2.2 Physiological Monitor

Prior to re-use, the physiological monitor should be cleaned as follows:

NOTE

- The PM monitor may be disinfected to comply with OSHA requirements for cleaning and decontaminating spills of blood and other body fluids. (Federal OSHA Standard on blood borne pathogens: 29 CFR 1910.1030, 12/6/91) **Wexcide** (Wexford Labs, Inc., Kirkwood Missouri) and **T.B.Q.** (Calgon Vestal Lab., Calgon Corp., St. Louis, Mo.) are disinfectants that meet the OSHA requirements, are EPA approved, and will not harm the outside of the physiological monitor. Only Wex-cide is recommended for disinfecting the inner surface of the display window. The disinfectants should be thoroughly rinsed away with water (do no immerse physiological monitor in water) after 10 minutes.
- The panel connectors of the physiological monitor have been specially designed to prevent water or other liquids from entering the monitor. However, liquids can get into the connectors. If liquid does enter the connectors it should drain out through a drain hole in the bottom. If moisture is present, dry the connectors with warm air and re-check all monitoring functions for proper operation.

1. Wipe the physiological monitor with a nearly dry cloth containing one of the mild cleaning solutions recommended in Table 12-1. Thoroughly wipe off any excess residual cleaning solution. Do not allow the cleaning solution or water to run into crevices or connector openings.
2. The cuff may be cleaned using common hospital disinfectants, including Cidex, bleach (1:10 solution), isopropyl alcohol, Lysol® solution, Phisohex®, Quatricide®, Virex® and Vesphene®. Wash gently with the solution, then rinse. Do not allow the solution to enter the cuff tubes, as this will interfere with the functioning of the cuff.

CAUTION

Do not allow the cleaning solution to run into crevices or connector openings. Isopropyl alcohol or other solvents should not be used for cleaning.

3. Cables, cuff tubing, and accessories, including the CO_2 sensor, can be wiped with a damp cloth moistened in a mild detergent solution.

Table 12-1. Cleaning Agents OK and Not OK to use on Physiological Monitor

O.K. to Use	Never Use
Warm Water	Butyl Alcohol
Hydrogen Peroxide Solution	Denatured Ethanol
Cidex®	Freon
Liquid Soap	Mild Chlorine Bleach Solution
Windex®	Isopropyl Alcohol
Formula 409®	Trichloroethane, Trichloroethylene
Fantastik®	Acetone
Coverage	Vesphene II
T.B.Q.	Enviroquat
Wex-cide	Staphene
	Misty

12.2.3 I-Stat

If the analyzer is placed on a wet surface or if any liquid is spilled on it, dry the analyzer immediately. If liquid enters the electronics compartment, the battery compartment, or the cartridge port, the analyzer may be damaged.

Clean the display screen with a soft dry tissue. Clean the case using a gauze pad moistened with a mild non-abrasive cleaner, detergent, soap and water, or alcohol; rinse using another gauze pad moistened with water and dry.

Decontaminate the analyzer whenever a specimen is spilled onto the analyzer. Wear gloves while performing the following procedure:

1. Prepare a 1:10 solution of household bleach by mixing one part of bleach with nine parts of tap water. This solution will maintain its germicidal action for a week.
2. Soak a few gauze pads in the bleach solution. Before use, squeeze the pads to remove excess solution.
3. Soften, then remove any dried blood with one or two of the gauze pads soaked in the bleach solution. Avoid scraping dried blood as contaminated particles may become airborne.
4. Clean the entire surface of the analyzer twice with gauze pads soaked in the bleach solution.
5. Rinse the surface of the analyzer with gauze pads moistened with tap water and dry.

CALIBRATION VERIFICATION AND THE i-STAT SYSTEM

INTRODUCTION

Calibration Verification is a procedure performed to confirm that the calibration of an instrument or test system has remained stable throughout the reportable range. In many countries, this procedure is called a linearity check. Because of the inherent stability of the i-STAT System, i-STAT does not make any specific recommendations for the calibration verification procedure. Therefore, it is the responsibility of the laboratory to determine when and how this procedure should be performed. The information presented below is intended to help the laboratory make this determination.

In the United States, laboratory regulations (CLIA) require that for tests categorized as High Complexity, a calibration verification procedure be performed and documented at least once every six months. For tests categorized as Moderate Complexity, the manufacturers instructions regarding calibration verification must be followed. The i-STAT System is categorized as Moderate Complexity. However, the College of American Pathologists (CAP) considers all tests to be High Complexity. The information presented below supports i-STAT's position that it is the cartridges, or more specifically, the sensors, rather than the analyzers that should be subject to the six-month check on the accuracy of the reportable range, and supports i-STAT's claim that all analyzers that pass the Electronic Simulator test are equivalent, which should preclude the testing of three levels, twice a year, on each and every analyzer on site.

In addition to the six-month time frame for a calibration verification procedure for High Complexity tests, CLIA and laboratory accrediting bodies in the US list the following as possible reasons to perform calibration verification:

- validate the reportable range of a test before the test system is put into use.
- verify that a change in reagent lot numbers does not affect either the reportable range or control values.
- troubleshoot when control values are out-of-range.
- verify that results have not been affected by maintenance or repair procedures.

STABILITY OF CALIBRATION IN THE i-STAT SYSTEM

The i-STAT System is a unit-use testing system. Components that cause shifts and drifts in results in multi-use analyzers: sensors (electrodes), calibration solution, fluid-handling channels and pumps, are housed in a disposable test cartridge. The sensors are exposed to sample only once, so there is no protein build-up which is a major cause for deterioration of sensor slope and the need to calibrate and/or verify calibration on a frequent basis in multi-use analyzers.

The stability and consistency of the manufacturing process allow the slope of the sensors to be programmed into the analyzer's software. A one-point calibration to set the intercept accounts for any day-to-day variation in testing conditions. When stored according to directions, the cartridges are stable up to the expiration date.

The analyzer houses the mechanical and electrical systems necessary to control fluid movement within the cartridge, control the temperature when measurements are performed at 37°C, measure barometric pressure, measure electrical signals generated by the sensors and display and transmit results. The analyzer's functions are factory calibrated to specifications that are programmed into the analyzer along with acceptability limits, which when exceeded cause the analyzer to display quality check messages or to display *** rather than results.

The accuracy of results and dependability of the internal quality check system depend upon the ability of the analyzer to take accurate and sensitive signal readings from the sensors. To check this function, i-STAT developed an electronic control device. The Electronic Simulator simulates two levels of electronic signals that stress the analyzer's signal detection function both below and above the reportable ranges. Injecting signals directly into the analyzer allows very tight control limits to be set. Control limits for liquid controls are set wide enough to allow for sensor-to-sensor variation. All analyzers that pass the Electronic Simulator test are equivalent and any variations in results are caused by within and between lot variations in the cartridges.

The combination of unit-use cartridges, inherently stable electronics of the analyzer, and reliability of the Electronic Simulator check provides the stability needed for a point-of-care testing system and reduces the need for frequent stability or calibration verification checks.

VALIDATING THE REPORTABLE RANGE

The accuracy of results over the entire reportable range could be assessed by testing the same patient samples on the new system and on a system with known accuracy and comparing results using an acceptable difference criteria. However, it is difficult to find samples that cover the low and high ends of the reportable ranges of many analytes. Ideally, the samples used to validate the ranges should have the same matrix as the patient samples. Tonometered blood can be used to validate the ranges for PCO_2 and PO_2. But for most analytes, there are no whole blood samples commercially available for this purpose.

Although the i-STAT Calibration Verification Set is aqueous-based, the target values have been determined over many lots of cartridges and results on these solutions when compared to the target values should indicate the performance of a particular lot of cartridges.

ASSESSING LOT-TO-LOT VARIATION

Lot-to-lot variation over the entire reportable range for any reagent system could be assessed by testing calibration verification solutions on old and new lots in parallel. This procedure should be suspended once it has been determined that lot-to-lot variation is acceptable. Quality controls samples with concentrations at decision points should always be used to assess new lots or reagent before results are reported.

Because the manufacturing process for the cartridges produces consistent lots with little lot-to-lot variation, i-STAT does not make any recommendations for this procedure. Each new lot of cartridges should be assessed using the i-STAT quality control solutions according to the procedure in the System Manual.

TROUBLESHOOTING

Should quality control sample results fall outside of the acceptable ranges, calibration verification samples with very low or very high concentrations could be helpful in characterizing a reagent problem. This information would be most valuable if the user could affect a change in the calibration of the test system to correct the problem.

The i-STAT System was designed so that the intended users, who are not familiar with laboratory procedures, cannot make any adjustments that would affect results. The characteristics of the sensors are well known and results of control solutions would be sufficient for Technical Support specialists to help users resolve control out-of-range problems.

VERIFYING THAT RESULTS HAVE NOT BEEN AFFECTED BY MAINTENANCE OR REPAIR PROCEDURES

In multi-use systems, reagents and samples are run through the analyzer and, therefore, there should be a method of checking that all components are performing together according to specifications after any one component is affected. Calibration verification solutions can be used to verify that the calibration or slope of the measuring system has not been affected by the maintenance or repair procedure.

The user cannot perform any maintenance procedures on the i-STAT System. However, the software in the analyzer is updated periodically – a procedure that potentially could cause a change in results. In fact, software updates are released to ensure that results do not change over time. Calibration verification solutions could be tested to verify that results have not been affected. This procedures should be suspended or replaced with controls once it has been determined that software updates do not affect results. Since i-STAT has been effectively updating software for over 10 years, this procedure is not part of i-STAT's recommended quality program.

Repaired and newly purchased analyzers are received with factory calibration. Again, the Electronic Simulator can better assure that the analyzer's most important function is within factory specifications than calibration verification or control solutions.

Testing calibration verification samples or comparing patient sample results on a new or repaired analyzer with an older analyzer will assess cartridge performance only. Any variations in analyzer performance will not be statistically discernable above the performance of the cartridges. When multiple analyzers are to be used at a facility, i-STAT recommends including at least two analyzers in any performance verification studies so that statistics reflect the "system."

RECOMMENDED CALIBRATION VERIFICATION PROCEDURE

i-STAT's Calibration Verification Set includes five levels of solutions for all tests except hematocrit. Reportable ranges can be verified using Levels 1, 3 and 5 since the concentrations in these solutions cover the low, mid and high areas of the ranges. All five levels can be used to increase confidence.

When performing the calibration verification procedure to meet a six-month calibration verification requirement, include each sensor and a representative selection of analyzers. When using the i-STAT Calibration Verification Set, triplicates should be tested since the insert ranges are based on the average of triplicate results.

Notes:

Calibration Verification or a linearity check for hematocrit can be performed using blood collected in lithium heparin tubes and manipulated to create three levels of hematocrit. Target values can be obtained from the bench top lab analyzer.

The upper limit of the reportable range for PO_2 is 800 mmHg. The highest PO_2 level in the i-STAT Calibration Verification set is just over 450 mmHg. Oxygen levels above 450 mmHg are so unstable in aqueous solutions that it would be impossible to make reliable measurements above 450 mmHg. Whole blood samples can be tonometered with 100% oxygen to create a sample around 700 mmHg at sea level.

Calibration Verification Sets are available through Integrated Medical Systems (IMS). Contact IMS support for ordering.

12.2.4 Fluid/Drug Infusion

When cleaning observe the following:

- Cleaning of the infusion pump should be in accordance with the instructions contained in USDOL OSHA 29 CFR 1910.1030-Bloodborne Pathogens.
- Use solutions of non-abrasive, non-staining detergent (i.e. commercially available, alcohol free, dishwashing liquid) well diluted with warm water. A 1:10 bleach to water solution is also recommended.
- Rinse with distilled or de-ionized water.
- Use soft, non-abrasive cloths, soft bristled brushes and/or non-abrasive, lint free swabs.

Pump, lower housing, slide link and latch

1. Wipe the pump using a cloth dampened with cleaning solution.
2. Remove the lower housing to access the pump's power assembly by pressing all four black release tabs simultaneously while pulling straight down.
3. Set the pump upright.
4. Spray the slide link and pumping latch area with cleaning solution.
5. Leave the pump upright and allow residue to soften.
6. Brush and/or swab the area again to remove residue.
7. Rinse thoroughly.
8. Air dry in upright position.

Air Sensor Recess

1. Wipe recess with a swab dampened with cleaning solution using a downward motion.
2. Remove excess moisture with a dry swab.

Optomodules

1. Clean optomodules with a lint free swab dampened with cleaning solution.
2. Rinse thoroughly using a lint-free swab dampened with water.
3. Remove excess moisture with a dry, lint-free swab or allow to air dry in an upright position.

CAUTION

Do not clean optomodules with isopropyl alcohol.

Valve Actuators

1. Gently clean the valve actuator and actuator seal using a lint free swab dampened with cleaning solution.
2. Gently rinse using a lint-free swab dampened with water.
3. Gently remove excess moisture with a lint-free swab, or allow to air dry in an upright position.
4. Inspect the exposed tips of the valve actuators for damage by lightly pushing the tips of the valve actuators side-to-side with dry swab. If the tip is not rigid, it is broken and must be replaced before using the pump.

12.2.5 Defibrillator

Cleaning of the Defibrillator should be in accordance with the instructions contained in USDOL OSHA 29 CFR 1910.1030-Bloodborne Pathogens.

12.2.6 Suction

1. After each use, with the unit running, spray a small amount of disinfectant directly into the vacuum inlet tubing fitting (which attaches to the filter).
2. Remove and replace suction bottle.
3. Disconnect and discard used external patient tubing and route new tubing. Ensure new tubing is not crimped, worn or cracked.
4. Remove and replace Bacterial/Overflow filter.

NOTE

If the unit has been operated without a filter or in the event of aspirate overflow, the pump head assembly should be removed, disassembled and disinfected at the next higher level of maintenance.

12.2.7 Ventilator

Cleaning of the ventilator should be in accordance with the instructions contained in USDOL OSHA 29 CFR 1910.1030-Bloodborne Pathogens (a 1:10 bleach to water solution is acceptable). Clean Ventilator and its components after every use in conjunction with readying the LSTAT for its next use.

1. Clean the control panel with a damp, soapy cloth and thoroughly dry with a lint-free cloth.
2. The compressor inlet filter housings are located on either side of LSTAT adjacent to external air and external oxygen fittings. Remove filter using a pair of tweezers or similar tool. Examine the filter for dirt, lint, or general wear. Replace if necessary. DO NOT attempt to clean this filter. Do not operate internal compressor without filter in place.
3. Dry all wet components.
4. Inspect the Vent Drain Hole in the foot portion of the stretcher footwell (on the patient left side) for obstructions. Clean out as necessary with dry, lint free rag.
5. Pressure hose connections should be wiped with a damp, soapy cloth and thoroughly dried with a lint free cloth.
6. Wipe the exterior wall with a damp, soapy cloth.

12.2.8 Oxygen

12.2.9 Electrical Power

Cleaning of the electrical cable and the five connectors should be in accordance with the instructions contained in USDOL OSHA 29 CFR 1910.1030-Bloodborne Pathogens (1:10 bleach to water solution is acceptable).

Do not allow chemical solution to contact pins and/or sockets and/or blades of connectors. Allow to air dry.

12.2.10 Environmental Control

Figure 12-1 shows the location of the ECS air inlet and filters. Figure 12-2 shows the ECS Particulate and EMI filters.

1. Check for adequate air exhaust.
2. Raise the louvers on the both sides of the head fairing to access the Particulate and EMI filters.
3. Remove and examine each of the filters for cleanliness and serviceability.
4. Clean and dry filters if dirty. (A filter is considered dirty if 25% of it is blocked. Clean with cold water and air dry). Replace filter if unserviceable, i.e., holes in filter, filter frame bent or cut so as not to fit properly in its frame and/or will not contain the filter, uncleanable.

NOTE
The Particulate filter faces the louver with EMI filter directly behind it.

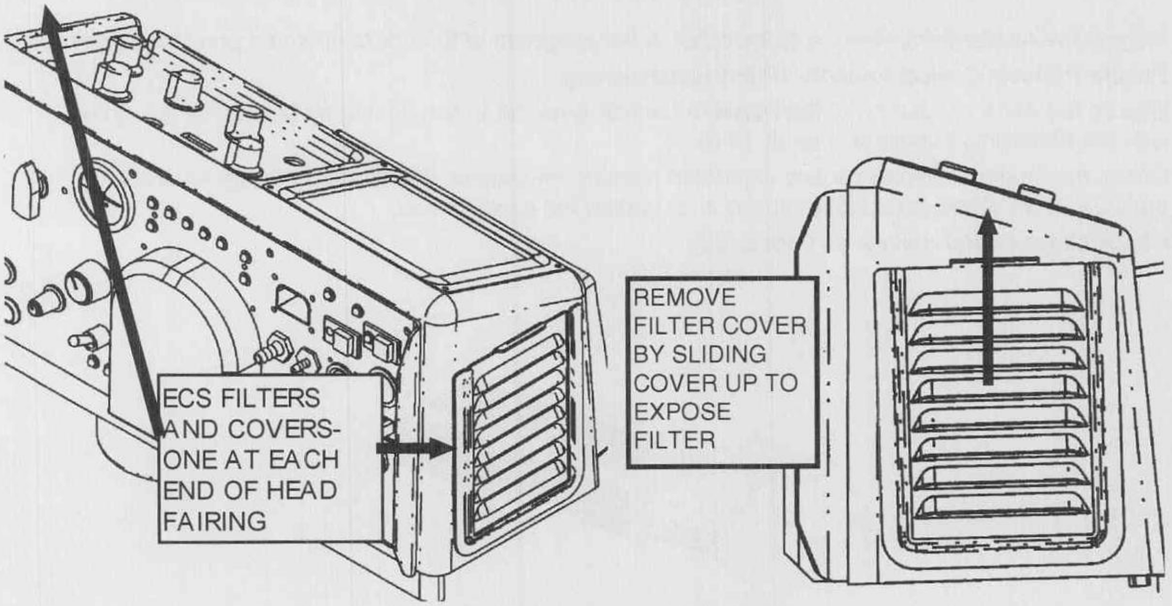

ECS FILTERS AND COVERS-ONE AT EACH END OF HEAD FAIRING
REMOVE FILTER COVER BY SLIDING COVER UP TO EXPOSE FILTER

Figure 12-1. ECS Air Inlet

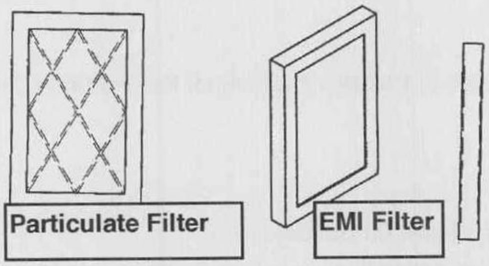

Particulate Filter
EMI Filter

Figure 12-2. ECS Air Filters

12.2.11 Secondary Display

1. Clean the Secondary Display Monitor by gently wiping the screen surface using a soft cotton cloth dampened with water or a mild solution of water and liquid detergent.

Caution

> The Stylistic display is not waterproof. Do not pour liquids on the pen tablet or wash the pen with a heavily soaked cloth.

2. Stow the clean and dry Secondary Display in its place in the Accessory bag.

12.3 Inspection

12.3.1 Physiological Monitor

1. Check the monitor for unusual wear or possible damage.
2. Check cables and hoses for cracks and frays.

12.3.2 I-Stat

The Portable Clinical Analyzer is a self-contained unit and as such can only be examined for exterior defects and tested using the Electronic Simulator (Figure 12-3).

1. Inspect the Analyzer for obvious defects that in the judgment of the operator would preclude its use.
2. Ensure Portable Clinical Analyzer IR link is functioning.
3. Ensure the Analyzer portion of the Portable Clinical Analyzer is functioning by testing the Analyzer with the Electronic Simulator (Figure 12-3).
4. Check the analyzer display for any expiration warning messages. If expiration messages are observed then obtain an updated analyzer or update the existing one.
5. Check batteries and replace as necessary.

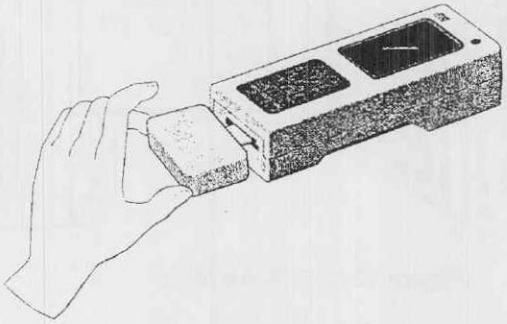


Figure 12-3. Insertion of Electronic Simulator into Portable Clinical Analyzer

12.3.3 Fluid/Drug Infusion

1. Inspect infusion pump outer surfaces for damage.
2. Inspect the infusion pump lower housing, slide link and latch for dried residue.
3. Inspect the air sensor recess for dried residue.
4. Inspect optomodules for damaged actuators, residue.

Any discrepancies noted in the following will require removal from service and repair actions undertaken.

5. When programming infusions verify the display:
   - Is complete and not blurred
   - Reads the same as described in CHAPTER 7.
   - Responds with the intended function for the intended key press.

12.3.4 Defibrillator

Visual Inspection

1. Visually inspect expiration date on the outside of the electrode package. Replace as necessary.

Operational Check #1

1. Power up LSTAT (Wait for LSTAT to complete initialization cycle).
2. Power up Defibrillator
3. Remove the electrodes.
4. Turn off POWER to Defibrillator.
5. Turn on POWER to Defibrillator and confirm the CHK ELCTRD light is lit.
6. Reconnect the Electrodes and Turn off POWER to Defibrillator.
7. Turn on POWER to Defibrillator and confirm that no diagnostics lights are lit.
8. If any lights are lit, return LSTAT for maintenance.
9. Turn off POWER to Defibrillator and the LSTAT.

Operational Check #2

1. Power up LSTAT.
2. Press and hold the DISCHARGE button while turning on power to the Defibrillator.
3. Confirm the CHK UNIT light is lit.
4. Release the DISCHARGE button and press POWER off to the Defibrillator.
5. Turn POWER on to the Defibrillator and confirm that no diagnostics lights are lit.
6. If any diagnostics lights are lit, return LSTAT for maintenance.
7. Press POWER to turn off the Defibrillator.

12.3.5 Suction

1. Verify that vacuum pump motor is operating.
2. Confirm operation of all indicators, meters gauges, and visual displays.
3. Ensure indicator rests on zero without vacuum applied.

12.3.6 Ventilator

1. Verify operating power.
2. Confirm that LCD display verifies presence of operating power.
3. Verify successful completion of SELF-CHECK.
4. Insure that all hoses, tubing, and fittings are properly connected.
5. Check end connection fittings for damaged threads and sharp edges. REPLACE if necessary, **do not** repair.
6. Inspect the compressor inlet filters located on both sides of the LSTAT in between the external air and O_2 ports (Figure 12-4).
7. Remove the filter using a pair of tweezers or similar tool.

CAUTION

- Use replacement filters only. Incorrect size or improper material may be sucked into the ventilator system
- Do not operate internal compressor without filter in place.

8. Inspect the filter for dirt, lint, and/or serviceability. Replace if torn, shrunk, hard or uncleanable.
9. Ensure presence of apnea hat valve in patient circuit connector on head fairing.

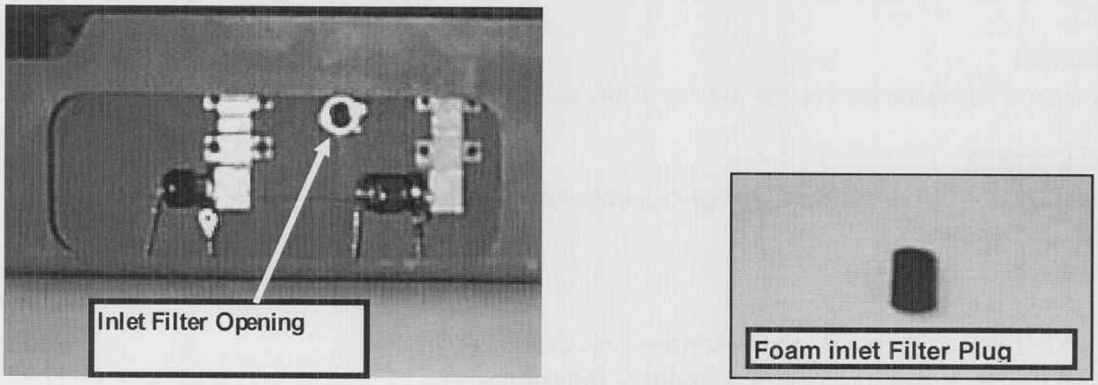

Inlet Filter Opening
Foam inlet Filter Plug

Figure 12-4. Compressor Inlet Filter

12.3.7 Oxygen

Internal Oxygen Supply Check

1. Toggle *SYSTEM POWER* to *ON*.
2. Place the Oxygen Switch to the ON position (Figure 12-5).

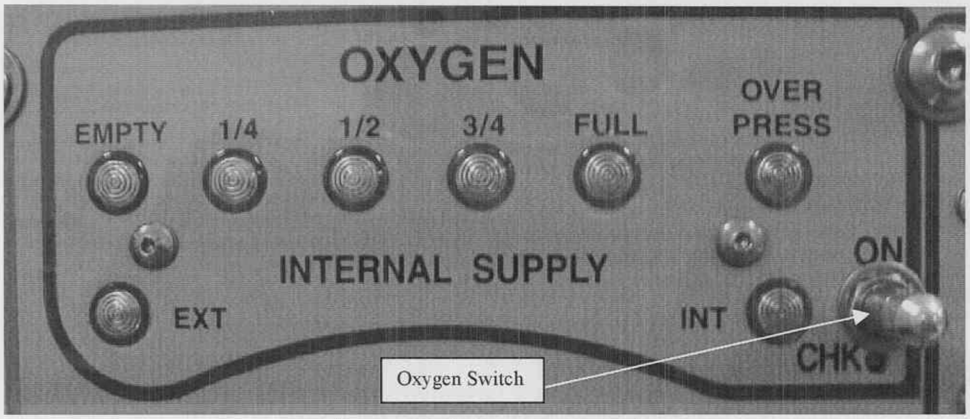

OXYGEN
EMPTY
1/4
1/2
3/4
FULL
OVER PRESS
INTERNAL SUPPLY
EXT
INT
ON
CHK
Oxygen Switch

Figure 12-5. Oxygen Switch

3. Check the status of the Oxygen lights:

Label	Light	Status
EXT	Steady Green	External O_2 system active
EMPTY	Flashing Red	Less than 514 psi (Less than 1/8).
1/4	Steady Yellow	Less than 1226 psi, greater than 514 psi (Less than 3/8; greater than 1/8).
1/2	Steady Green	Less than 1939 psi, greater than 1226 psi (Less than 5/8; greater than 3/8).

Label	Light	Status
3/4	Steady Green	Less than 2651 psi, greater than 1939 psi (Less than 7/8; greater than 5/8).
FULL	Steady Green	Less than 3300 psi, greater than 2651 psi (Less than 3300 psi, greater than 7/8).
OVER PRESS	Flashing Red	O_2 system exceeds 3300 PSI. (Turn Oxygen Switch OFF and remove and replace O_2 bottle.)
INT	Steady Yellow	O_2 system pressurized

4. Verify Oxygen gauge shows 3,000 psi and that Operator Interface Panel shows "FULL". If not "FULL" then install a fully charged oxygen cylinder and recheck the LED's and the gauge.

External Oxygen Supply Check

1. Hook up to an external oxygen source.
2. Verify that the internal oxygen bottle is turned off (knob closed fully clockwise).
3. Set the Bypass Flow Meter for 2 liters per minute.
4. Plug in Bypass Flow Meter for 5 seconds to verify rush of air.
5. Disconnect External connection and open internal connection. Verify flow through Bypass meter for 5 seconds.
6. Close off internal supply and unplug oxygen Bypass Flow Meter.

Oxygen Flow with Ventilator

1. Turn on Ventilator to the ASSIST mode.
2. Set Ventilation rate to 10 BPM, ½-second inspiration time and 500 ml Tidal Volume.
3. Set the air/oxygen mixture to 100%.
4. Verify that no oxygen LOW/FAIL alarm is present.
5. Turn Oxygen Switch OFF and verify that the Oxygen LOW/FAIL alarm is activated.
6. Turn off ventilator.

12.3.8 Electrical Power

1. Inspect the electrical cables for any signs of fraying or cuts. Repair or replace if necessary.
2. Make sure all of the circuit breakers are pushed in the foot compartment before use.

12.3.9 Environmental Control

1. Check for adequate air exhaust.
2. Raise the louvers on the both sides of the head fairing and verify that the Particulate and EMI filters are in place and then lower the louvers back in place.

12.4 Unit Prep/Set-up

12.4.1 LSTAT

Charging the Batteries

1. Ensure all subsystems are off.
2. Ensure SYSTEM POWER switch is in the OFF position.
3. Connect LSTAT to external power utilizing the appropriate adapter and the external hook-up procedures (Section 2.2.3).
4. Toggle the TRICKLE CHARGE switch located in the Foot Fairing to the ON position.
5. Allow LSTAT to re-charge for 24 hours.
6. Terminate the recharge process by toggling the TRICKLE CHARGE switch to the OFF position.
7. Disconnect the power cable adapter from the external power source and the power cable.

8. Disconnect the power cable from the LSTAT.

> NOTE
>
> - Battery recharge may be terminated at any time.
> - The battery group is fully recharged when the BATTERY CAPACITY FULL light is lit on the side Indicator panels. A complete recharge requires approximately 24 hr.
> - If the battery is not fully depleted only a partial recharge may be necessary.

12.4.2 DDLS

Lamp Test

1. Press LAMP on the Indicator Panel (Figure 12-6)
2. Observe all LEDs illuminate.

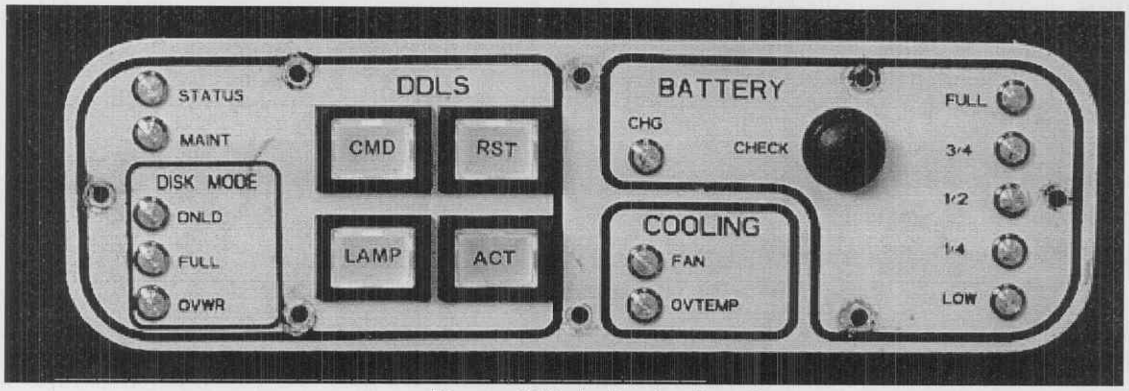


Figure 12-6. Indicator Panel

DDLS Operational Check

1. Check that the Data Entry and Display Panel is functioning by menuing through the displays.
2. Check current time is set. To set the time, refer to Section 2.1.7, Setting Data and Time.

12.4.3 Physiological Monitor

Physiological Monitor Power

1. Make sure that the *SYSTEM POWER* switch is *ON.*
2. On the head fairing, press the *PM PWR* button to turn on the physiological monitor (Figure 12-7).
3. Observe the Main Menu is displayed in the physiological monitor display.

> NOTE
>
> - The window will display start-up information while it performs a self-test.
> - If an error is detected during start, an error message window will appear.
> - Refer to Table 4-15 for error handling.
> - If information does not appear on the display, the contrast may be set too low. Adjust the display contrast. If the display still appears blank, press *PM PWR* to turn off the monitor, and press *PM PWR* to turn it back on. If the monitor screen remains dark, the physiological monitor may need servicing.
> - If any Menu option does not appear on the display, press the *MAIN MENU* button.

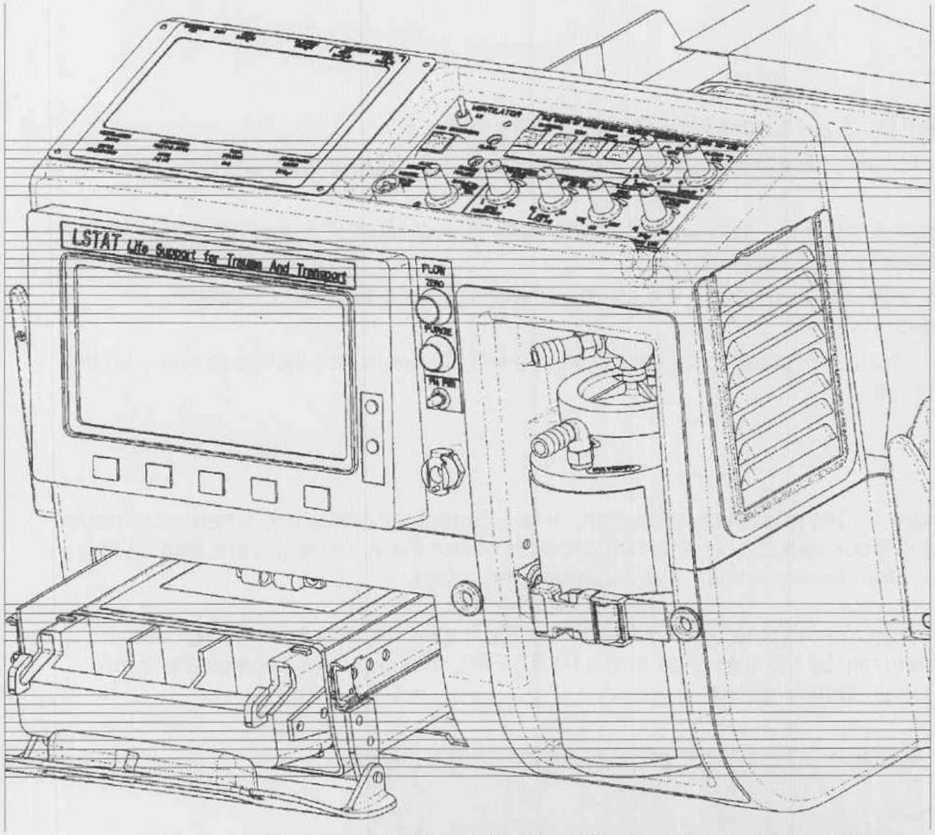

LSTAT Life Support for Trauma And Transport
FLOW
ZERO
PURGE
VENTILATOR

Figure 12-7. Physiological Monitor Controls and Display

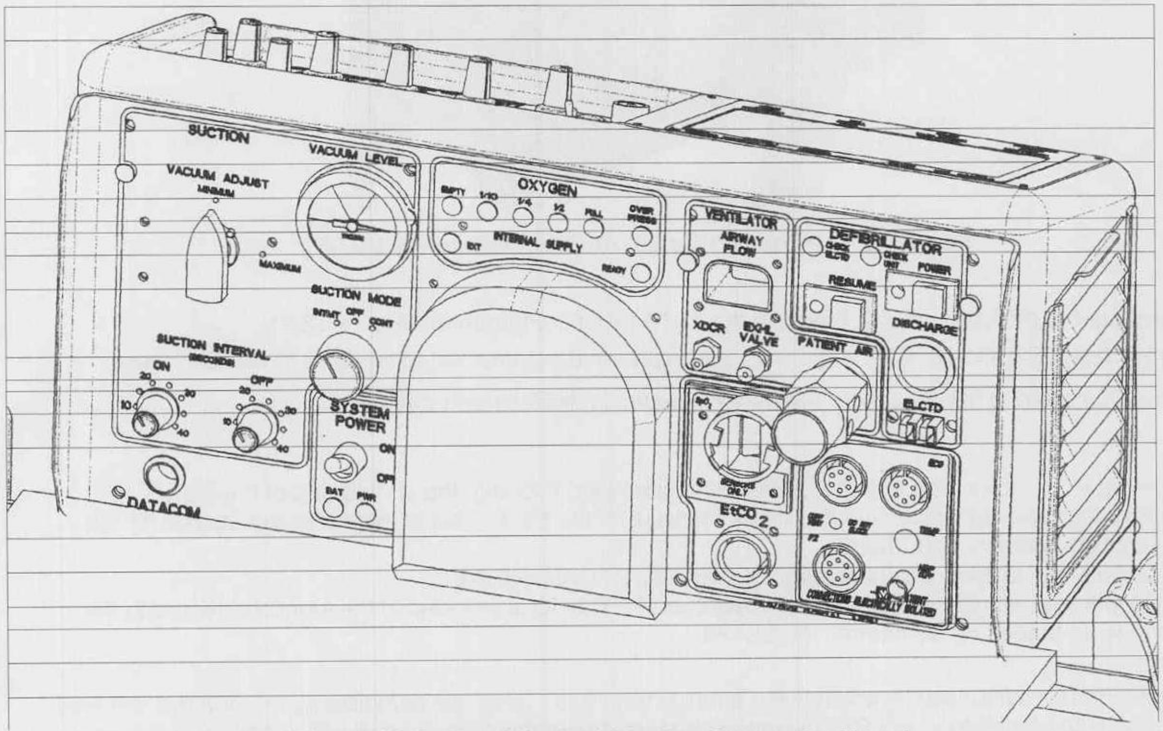

SUCTION
VACUUM ADJUST
MINIMUM
MAXIMUM
VACUUM LEVEL
OXYGEN
EMPTY
1/10
1/4
1/2
FULL
OVER PRESS
EXT
INTERNAL SUPPLY
READY
SUCTION MODE
INTMT
OFF
CONT
SUCTION INTERVAL
(SECONDS)
ON
OFF
SYSTEM POWER
ON
OFF
BAT
PWR
DATACOM
VENTILATOR
AIRWAY FLOW
XDCR
EXHL VALVE
PATIENT AIR
DEFIBRILLATOR
CHECK ELCTD
CHECK UNIT
POWER
RESUME
DISCHARGE
ELCTD
SENSORS ONLY
EtCO2
ECG
TEMP
CONNECTIONS ELECTRICALLY ISOLATED

Figure 12-8. Physiological Monitor Connector Panel

ECG Preparation

1. Take the ECG cable and ECG electrodes from the accessory bag.
2. Inspect the ECG cable for wear, breakage, or fraying. Replace if the cable shows any signs of damage.
3. Connect the ECG cable into the ECG connector on the Physiological Monitor Panel located on the Operator/Patient Interface Panel (Figure 12-8).
4. Support the ECG cable so it does not stress the electrode wires, electrode wire/ECG cable connectors, or electrodes.
5. If an ELECTROSURGICAL unit is going to be used, place the ECG cable and electrode wires so that interference will be minimal.

12.4.4 I-Stat

The Portable Clinical Analyzer (PCA) has no on/off switch. It is automatically activated when a cartridge is inserted. The PCA automatically deactivates after 45 seconds of inactivity. Pressing the display key activates the display screens for viewing results and accessing the menu.

Verify the performance of the PCA using the I-STAT Electronic Simulator. Quality tests at two signal levels are performed automatically by the simulator and a PASS/FAIL message indicates whether the PCA's measurements are within specifications.

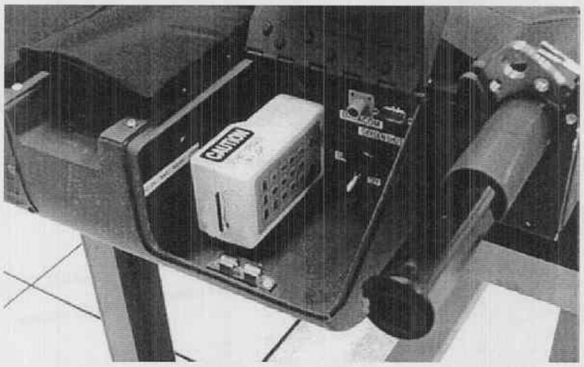


Figure 12-9. Portable Clinical Analyzer within the LSTAT

1. Remove the PCA from the IR cradle in the LSTAT foot compartment (Figure 12-9).
2. Press the DIS button if "SIM" appears, then insert the Electronic Simulator for a 120-second test.
3. The PCA utilizing the Electronic Simulator is tested in the following manner:

Position the PCA face up and the Electronic Simulator with "i" facing the slotted end of the PCA.
Insert the Electronic Simulator into the slot in the base of the PCA. This is the same slot utilized for the insertion of the analysis cartridges.
The PCA will then display the message: "CONTACTING CARTRIDGE".
The PCA will then display a prompt for an operator ID. This ID is included in the simulator record in the PCA and is up loaded on demand to the LSTAT.

A completion bar will be displayed showing a range from 0 to 120 seconds indicating that the test will take 120 seconds to complete. If a "LCK" message appears during this time, then the PCA battery is too weak to proceed with the test. Additionally, the following message will be displayed: "DO NOT REMOVE CARTRIDGE, ANALYZER NOT RESET, REPLACE BATTERIES". Replace the batteries leaving the simulator in the PCA and allow the test to continue. If the PCA displays the message: "ANALYZER INTERRUPTED, USE ANOTHER CARTRIDGE", then remove and replace the Electronic Simulator.

A "PLEASE WAIT" message will be displayed followed by "ELECTRONIC SIMULATOR". The completion bar will be displayed with "0" on the left and "120" on the right accompanied by the message "TIME TO RESULTS".

> **NOTE**
> A whining noise may be heard (in a quiet environment) from the PCA at this time. This is normal, as it is the sound of the internal motor being activated for the test.

At the conclusion of the test the following messages should be display:
"ELECTRONIC SIMULATOR"
"PASS"
"READY FOR USE"

If the test fails, then an error message will be displayed and further action may be required. This may include running a cartridge and re-running the simulator, updating the software or returning the PCA for repairs. See Chapter 10 for additional diagnostic information.

12.4.5 Fluid/Drug Infusion

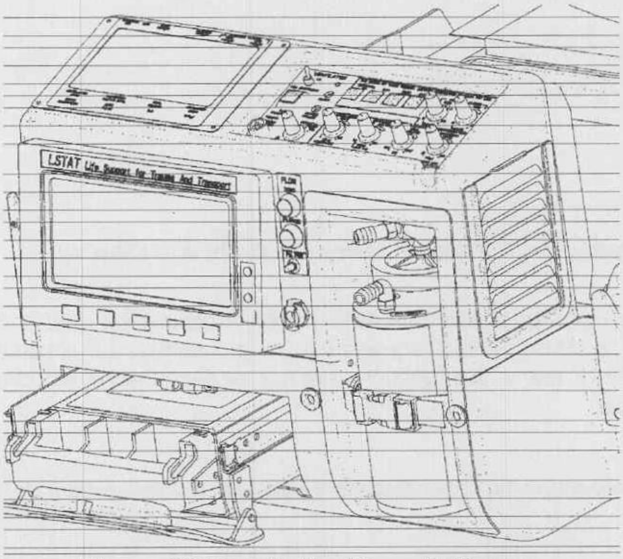
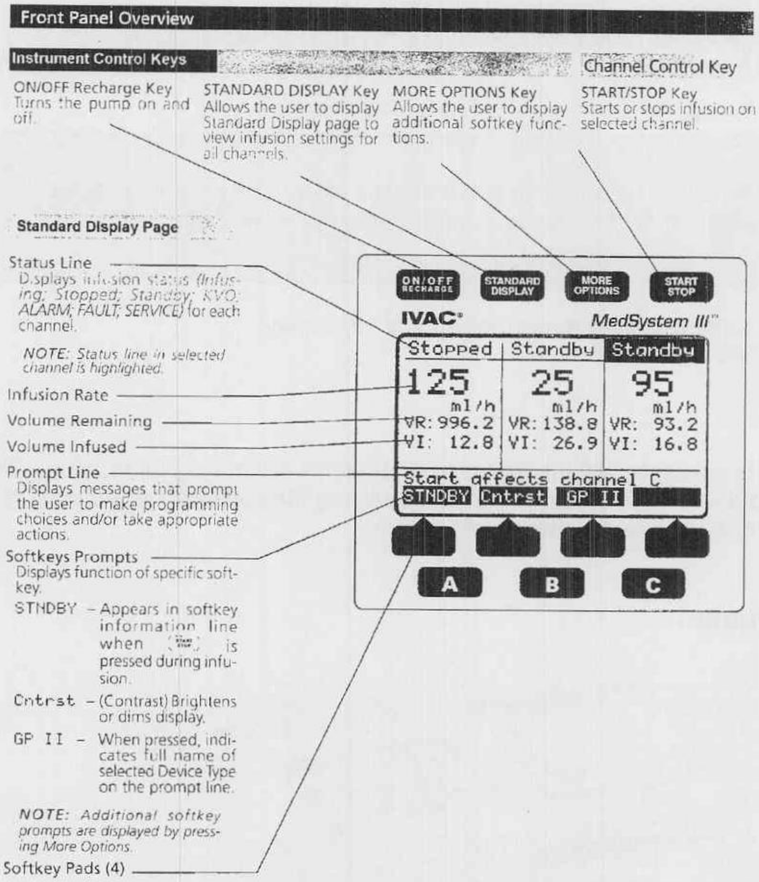


Figure 12-10. Infusion Pump in Drawer



Front Panel Overview

Instrument Control Keys

ON/OFF Recharge Key
Turns the pump on and off.

STANDARD DISPLAY Key
Allows the user to display Standard Display page to view infusion settings for all channels.

MORE OPTIONS Key
Allows the user to display additional softkey functions.

Channel Control Key

START/STOP Key
Starts or stops infusion on selected channel.

Standard Display Page

Status Line
Displays infusion status (*Infusing; Stopped; Standby; KVO; ALARM; FAULT; SERVICE*) for each channel.

NOTE: Status line in selected channel is highlighted.

Infusion Rate

Volume Remaining

Volume Infused

Prompt Line
Displays messages that prompt the user to make programming choices and/or take appropriate actions.

Softkeys Prompts
Displays function of specific softkey.

STNDBY – Appears in softkey information line when (▭) is pressed during infusion.

Cntrst – (Contrast) Brightens or dims display.

GP II – When pressed, indicates full name of selected Device Type on the prompt line.

NOTE: Additional softkey prompts are displayed by pressing More Options.

Softkey Pads (4)

Figure 12-11. Infusion Pump Controls and Display

These tests are recommended prior to clinical use, after repair or calibration, and annually as part of annual preventive maintenance. When a test requires a primed cassette, it is recommended that saline solution be used for such tests. If any of the functions are not as described in the check procedures, then the instrument requires service.

Do not perform any of the following tests while the system is in use on a patient.

A. Power-up Test

Charge the instrument for at least one hour before performing this test.
Proceed with the power-up test as follows:

1. Remove any cassettes installed in the instrument.
2. Turn the instrument on and verify proper power-up.
3. The instrument performs initial self-test during power-up; and, if it detects any problems, it will indicate a fault.
4. Check audio and keypad operation by ensuring there is a soft beep for each key press.
5. Press any key and ensure the LCD backlight turns on.

NOTE: *For a complete memory self-test, the instrument should be turned on for a minimum of 10 minutes for the Model 2860 and 18 minutes for the Model 2863 instruments. It is not necessary for the unit to be pumping to perform this test.*

B. Cassette and Sensor Test

This test verifies the proper functioning of the cassette and latch sensors, as well as the latching mechanisms. Repeat the following procedures for all three channels (A, B, and C).

1. With the instrument off, remove any cassettes that are installed in the instrument.

2. Turn on the instrument.
3. Verify that the pump latch mechanism of each channel returns to the Home position at the top of the stroke (nearest to the chassis).
4. Press the channel select key (A, B, or C), and then press the START/STOP key. A two-tone advisory will sound, and the highlighted message *Install Cassette* will appear in the prompt line near the bottom of the screen.
5. Install a primed cassette the appropriate channel (A, B, or C), but do not push the cassette slide clamp into place (see Figure 12-12). Ensure that there are no air bubbles.
6. Again press the START/STOP key. A two-tone sound will be emitted, and the message *Push slide clamp in* will appear at the bottom of the page.
7. Push the cassette slide clamp in (see Figure 12-13), and seat the tubing collar in the recess below the cassette. Three beeps will sound to indicate correct cassette installation and fluid in the sensor pathway. The cassette should latch easily and smoothly. If the air-in-line sensor detects air when a cassette is installed, a *Check Air Sensor* advisory will be displayed.
8. Press the START/STOP key. The message *Infusing* will appear on the channel status line.
9. While the channel is pumping, pull out the cassette slide clamp. You will hear a repeating four-beep audio alarm and the red LEDs will blink. Infusion will stop and the display will indicate a *Cassette Not Latched* alarm.
10. Remove the cassette. The alarm display should read *Cassette Removed.* Reset the alarm by pressing the channel select key (A, B, or C) for the channel in use, and press the CANCEL softkey.

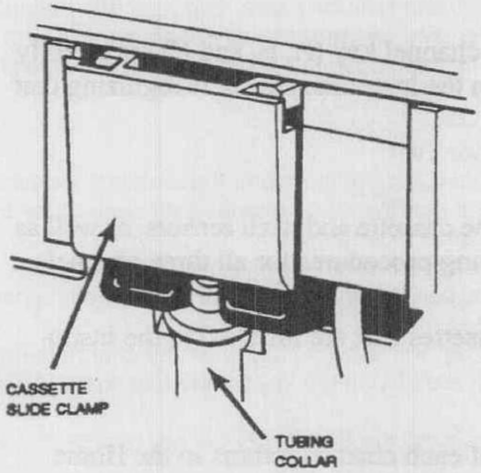


Figure 12-12

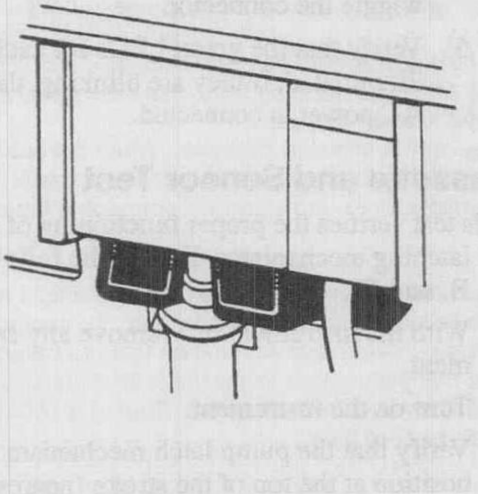


Figure 12-13

C. Patient-side Occlusion Detector Test

This test verifies the proper functioning of the alarm, which detects occlusion between the instrument and the patient. Repeat the following steps for each of the three channels, A, B, and C.

1. Connect a set to a fluid container and prime. Ensure there are no air bubbles.
2. Ensure the instrument is turned on.
3. Install the primed set.
4. Press the appropriate channel key (A, B, or C) to select the programming page for the channel to be tested.
5. Set the infusion rate for the selected test channel to 125 ml/h, and set the volume remaining to 100 milliliters.
6. Ensure that the roller clamp is open and caps are removed. Press the START/STOP key and verify that fluid is flowing.
7. Fold and pinch the patient-side tubing just below the instrument.
   When the patient-side occlusion is detected, the Standard Display will show an alarm for the test channel and will also show the message *Patient Side Occluded.* The red LED in the key for the test channel will blink, and an audible four-beep alarm will sound.
8. Release the tubing and press the START/STOP key to reset the alarm.

NOTE: *A more accurate patient-side occlusion test can be performed by configuring the instrument in the Controller Pressure Device Type, which has an absolute nominal occlusion pressure of three feet of water. Use a set which contains no filters or check valves, and which has macro bore tubing on the patient side. Set the infusion rate for 1 ml/h, and raise the patient-side tubing outlet two feet, two inches above the cassette. The channel should not sound an alarm. Next, slowly raise the tubing outlet three feet, eight inches above the cassette. The channel should sound an alarm within 10 seconds.*

D. Fluid-side Occlusion Detector Test

This test verifies the proper functioning of the alarm that detects occlusions between the instrument and the fluid container. Repeat the following procedure for each of the three channels, A, B, and C.

1. Install a primed set in the selected channel.
2. Start the selected channel at 125 ml/h.
3. Close the roller clamp between the instrument and the fluid container. The occlusion should be detected within two minutes.
4. The Standard Display screen will show an alarm for the channel under test and also the message *Fluid Side Occluded.* The red LED in the key for the test channel will blink, and an audible four-beep alarm will sound.
5. Open the roller clamp and press the START/STOP key to reset the alarm.

E. Air-in-line Detector Test

This test verifies the proper functioning of the alarm which detects air in a line. Repeat the following procedure for each of the channels, A, B, and C.

1. Disconnect the drip chamber from the solution bottle, or inject a large air bubble into the tubing via the upstream y-site.
   NOTE: *The injected air bubble size should be approximately twice the threshold value of the air detector plus one milliliter to fill the cassette air trap. For example, if the threshold is 500 microliters, then inject a 2-millitliter air bubble.*
2. Press the START/STOP key on the selected cassette. When the bubble is pumped through the cassette, the Standard Display should allow an alarm for the channel under test with the message, *Air In Line.* An audible four-beep alarm will sound and the red LEDs will blink.

F. Volume Accuracy Test

Accuracy of fluid delivery is determined by measuring the volume of fluid delivered over a known time period and comparing this measurement to the expected value. To ensure accurate measurements during this test, a volumetric glass burette (class A) must be used to collect the fluid. The infusion time interval, which is measured manually with a stopwatch with a precision of 0.1 second, must be 180 seconds are greater to minimize measurement errors. During a 180-second test, a one-second error by the operator results in an error of 0.6%.

The expected volume is calculated from the programmed rate and the measured time interval. The volume collected should be large enough to minimize errors in reading the burette. See Table 12-2 for the test parameters recommended by the AAMI proposed infusion device standard.

WARNING

Proper operation of the valve actuator return springs is essential for accurate fluid delivery when using negative input pressures. Negative input pressures occur as a result of negative head heights, viscous solutions, or syringe use.

Checking the spring function is accomplished by testing volume accuracy, using conditions of negative head height (at least –2.5 feet) and a rate greater than 275 ml/h. These conditions are recommended for annual functional tests, or if the valving mechanism was disassembled.

Table 12-2. Volume Accuracy Test Parameters

Rate (ml/h)	Minimum Collection Volume (ml)	Nominal Collection Time (min.)	Burette Size (min.)
5	10	120	10
10	10	60	10
50	25	30	25
100	25	15	25
250	50	12	50
500	50	6	50
999	50	3	50

NOTES:

1. Interpolation shall be to the next lower specified flow rate's collection volume, and collection time shall be the collection volume divided by the flow rate.
2. If the flow rate to be tested falls between two specified rates, choose the collection volume for the next lower rate. For example, to test 150 ml/h, choose a collection volume of 25 ml in a burette of 25 ml, with the resulting collection time being 10 minutes.

☐ **Test Equipment Setup**

1. Obtain a new set and connect it to a 500-milliliter container, which is at least half full. Prime the set and eliminate all air.
2. Connect the apparatus as shown in Figure 12-14. Use a volumetric burette marked in 0.1-milliliter increments (class A glassware).
3. Install the cassette into the channel being tested. If testing valve actuator springs, adjust the fluid level in the container to at least 2.5 feet below the cassette.

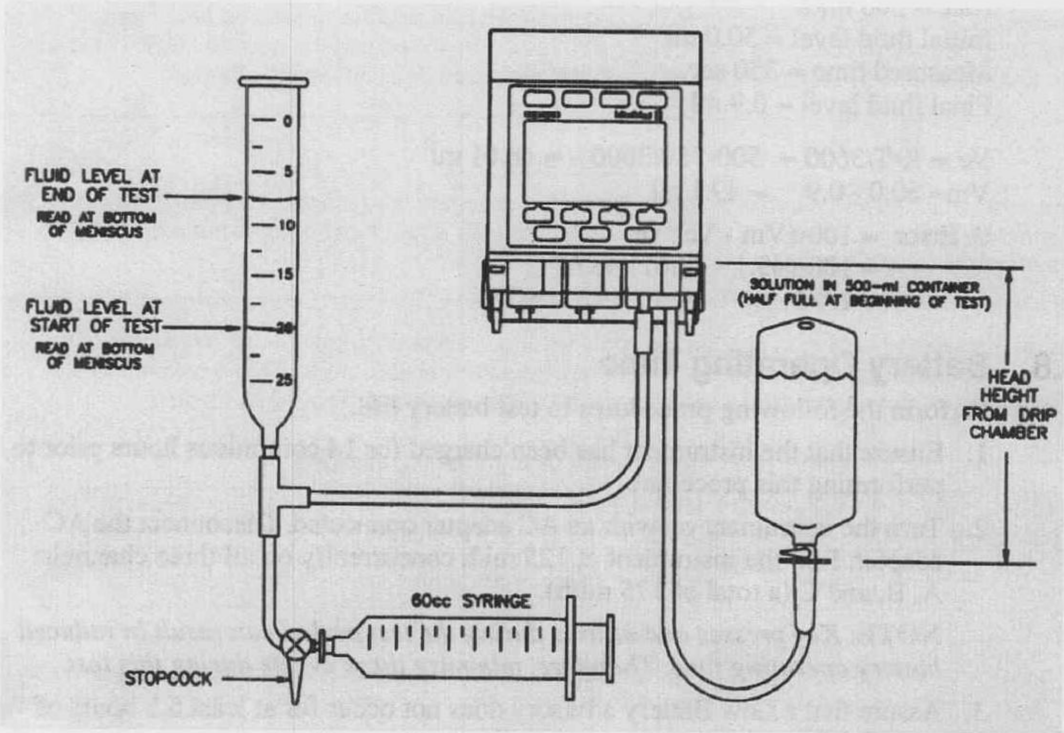

FLUID LEVEL AT END OF TEST
READ AT BOTTOM OF MENISCUS
FLUID LEVEL AT START OF TEST
READ AT BOTTOM OF MENISCUS
0
5
10
15
20
25
SOLUTION IN 500-ml CONTAINER (HALF FULL AT BEGINNING OF TEST)
HEAD HEIGHT FROM DRIP CHAMBER
60cc SYRINGE
STOPCOCK

Figure 12-14. Test Equipment Setup

- ☐ **Calculations**

Vm = Volume measured (ml) = (Initial fluid level – Final fluid level)
R = Rate (ml/h)
T = Time interval measured (seconds)
Ve = volume expected (ml)

Ve = R•T/3600
% Error = 100•(Vm - Ve)/Ve

- ☐ **Procedure**

1. Set the rate to the desired value for the channel being tested. Set the volume remaining greater than the expected volume (e.g., 100 ml) to ensure the infusion does not switch to a keep vein open (KVO) rate during testing.
2. Open the stopcock to the syringe and adjust the bottom of the meniscus to a convenient level. Record this level. Close the stopcock.
3. Simultaneously start the infusion and stopwatch.
4. When the infusion time is near nominal collection time, simultaneously stop the infusion and stopwatch.
5. Read the fluid level at the bottom of the meniscus and record this value. Read the stopwatch time and record the value.
6. Calculate the volume delivered, the volume expected, and the percent of error.

Example:
Rate = 500 ml/h
Initial fluid level = 50.0 ml
Measured time = 350 sec.
Final fluid level = 0.9 ml

Ve = R•T/3600 = 500•350/3600 = 48.61 ml
Vm = 50.0 – 0.9 = 49.1 ml
% Error = 100•(Vm – Ve)/Ve
= 100•(49.1 – 48.61)/48.61
= 1.0%

G. Watchdog Audio Test

Manually test the Watchdog Alarm Audio from the Standard Display. Press the More Options button several times until a softkey labeled Demo WD appears. Press this key and follow the directions on the screen for completing the Watchdog Test.

12.4.6 Defibrillator

Visual Inspection

Visually inspect expiration date on the outside of the electrode package. Replace as necessary.

Operational Check #1

1. Power up LSTAT.
2. Power up Defibrillator
3. Remove the electrodes.
4. Turn off POWER to Defibrillator.
5. Turn on POWER to Defibrillator and confirm the CHK ELCTRD light is lit.
6. Reconnect the Electrodes and Turn off POWER to Defibrillator.
7. Turn on POWER to Defibrillator and confirm that no diagnostics lights are lit.
8. If any lights are lit, contact IMS support.
9. Turn off POWER to Defibrillator and the LSTAT.

Operational Check #2

1. Power up LSTAT.
2. Press and hold the DISCHARGE button while turning on power to the Defibrillator.
3. Confirm the CHK UNIT light is lit.
4. Release the DISCHARGE button and press POWER off to the Defibrillator.
5. Turn POWER on to the Defibrillator and confirm that no diagnostics lights are lit.
6. If any diagnostics lights are lit, contact IMS support.
7. Press POWER to turn off the Defibrillator.

12.4.7 Suction

1. Toggle *SYSTEM POWER* to ON.
2. On the SUCTION Panel (Figure 5-2), turn the *POWER MODE* knob to INTMT to verify intermittent operation.
3. Listen to verify suction pump begins operation.
4. Turn the *POWER MODE* knob to CONT to verify continuous operation.
5. Listen to verify suction pump begins operation.
6. Test the *VACUUM ADJUST* for correct operation at various vacuum settings.

Suction Bottle Connection

A disposable hydrophobic, bacteria overflow filter is provided for use with the collection bottle. This filter connects between the Vacuum Inlet Fitting and the bottle. This filter should be replaced when discoloration of its membrane occurs, the membrane contacts aspirate, or following 150 cumulative hours of use. This filter is designed to retain bacteria that would otherwise be exhausted into the immediate vicinity. The filter's retention of aerosolized aspirate will create more resistance to airflow. It is important that the operator be aware of this and replaces the filter accordingly.

Disposable collection bottles traditionally include a built-in filter and may be used. It is not necessary to use the disposable filter in conjunction with disposable bottles. Reusable bottles should be used with the disposable filter to prevent inadvertent overflow, damage or contamination of the pump mechanism.

1. Insure that all hoses and fittings are properly connected (Figure 12-16).
2. Verify that collection bottle lid is properly secured.
3. Verify there are no kinks in tubing.

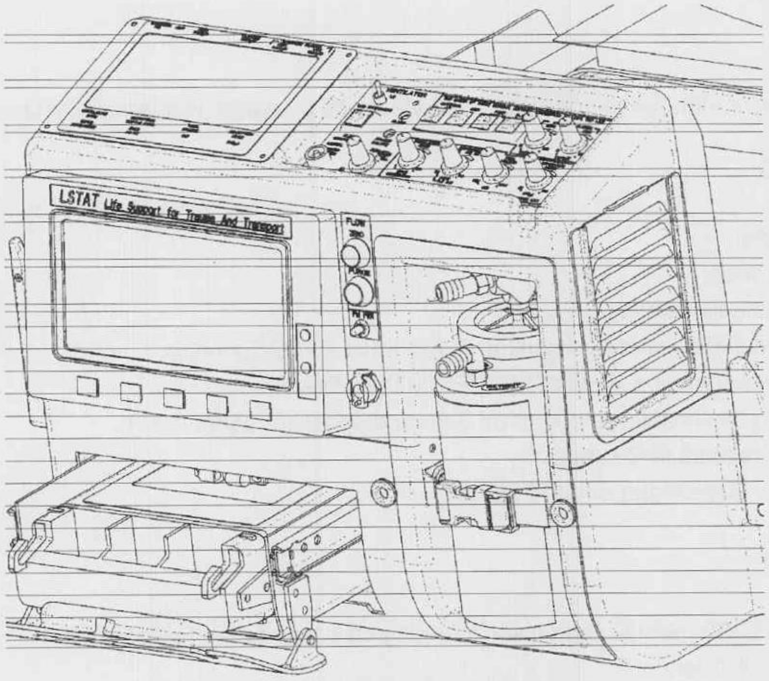
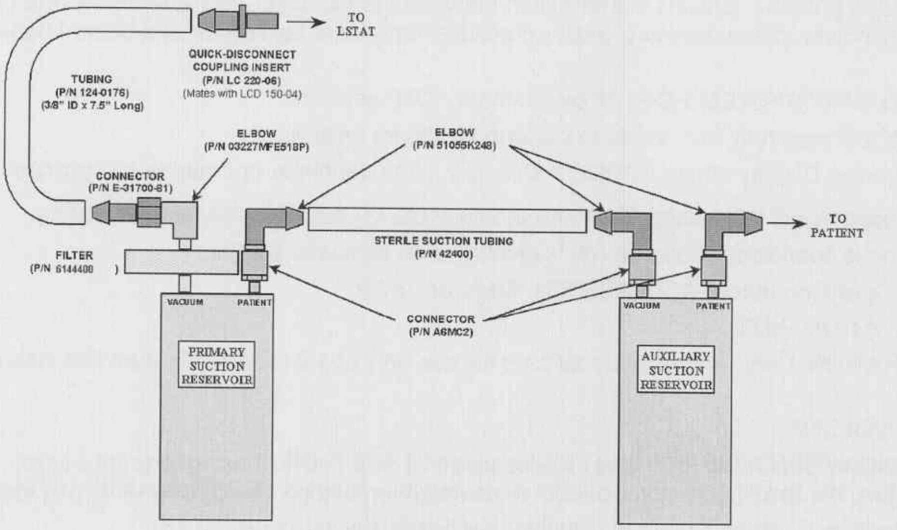


Figure 12-15. Suction Bottle Location

Auxiliary Bottle Connection

An auxiliary collection bottle may be used in series with the main suction bottle.

1. Take the auxiliary suction bottle holder assembly, secondary bottle, fittings and tubing from the accessory bag.
2. Attach the bottle holder assembly to one of the four IV pole holes located on the sides of LSTAT.
3. Install the auxiliary bottle in the bottle holder assembly and secure with the quick release latch.
4. Attach appropriate patient suction equipment to the auxiliary bottle.
5. Connect the auxiliary bottle to the main suction bottle as depicted in Figure 12-16


TO
LSTAT
QUICK-DISCONNECT
COUPLING INSERT
(P/N LC 220-06)
(Mates with LCD 150-04)
TUBING
(P/N 124-0176)
(3/8" ID x 7.5" Long)
ELBOW
(P/N 03227MFE518P)
ELBOW
(P/N 51055K248)
CONNECTOR
(P/N E-31700-81)
TO
PATIENT
STERILE SUCTION TUBING
(P/N 42400)
FILTER
(P/N 6144400)
VACUUM
PATIENT
CONNECTOR
(P/N A6MC2)
VACUUM
PATIENT
PRIMARY
SUCTION
RESERVOIR
AUXILIARY
SUCTION
RESERVOIR

SUCTION RESERVOIR ASSEMBLIES - LSTAT MODEL 9602/3

J.
Pawlowski
4/10/98

Figure 12-16. Suction Bottle and Auxiliary Bottle Connection

6. Toggle *SYSTEM POWER* to ON.
7. On the SUCTION Panel (Figure 12-17), turn the *POWER MODE* knob to INTMT to verify intermittent operation.
8. Listen to verify suction pump begins operation.
9. Turn the *POWER MODE* knob to CONT to verify continuous operation.
10. Listen to verify suction pump begins operation.
11. Test the *VACUUM ADJUST* for correct operation at various vacuum settings.

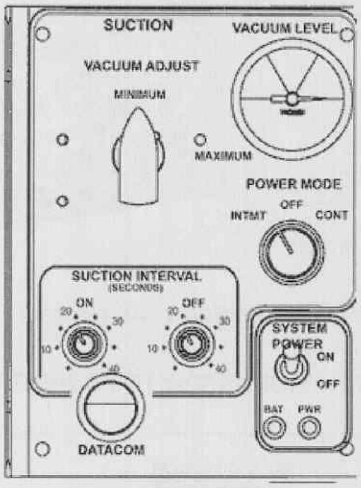

SUCTION
VACUUM LEVEL
VACUUM ADJUST
MINIMUM
MAXIMUM
POWER MODE
OFF
INTMT
CONT
SUCTION INTERVAL
(SECONDS)
ON
OFF
10
20
30
40
SYSTEM
POWER
ON
OFF
BAT
PWR
DATACOM

Figure 12-17. SUCTION Panel

12.4.8 Ventilator

The ventilator undergoes a self-checking process every time its MODE Selector Switch is turned from "OFF" to ACV, SIMV, or CPAP, or from CAL to ACV, SIMV, or CPAP. After the initial SELF-CHECK is performed, self-checking is not repeated if the operator turns the MODE Selector Switch to another operating mode position.

The SELF-CHECK process consists of interaction between the ventilator microprocessor and peripheral circuitry to verify power status, memory check, pressure transducer calibration and control panel settings.

1. Toggle the LSTAT SYSTEM POWER switch to the "ON" position.
2. Turn the MODE switch to CAL mode to perform Ventilator calibration.
3. If the Electronics Display shows: MODE = CAL OK , then ventilator operations can proceed.
4. If external oxygen will to be used, then turn the select % O_2 switch to the desired setting.
5. If external air is connected, observe ON is displayed on ventilator display.
6. Select the Operating mode; ACV (ASSIST), SIMV or CPAP.
7. Set VENTILATION RATE.
8. Set INSPIRATION TIME. If your protocol calls for use only at 1:2 I:E RATIO, then this step can be skipped.
9. Set TIDAL VOLUME.
10. Set the AIR/OXYGEN MIXER for and FIO_2 between 21 and 100%. If using internal oxygen, or with 100% oxygen, the air/oxygen mixer control remains either fully counterclockwise or fully clockwise.
11. Connect Ventilator Patient Circuit to ventilator connector panel (Figure 12-18).
12. If the Flow Sensor is installed, press the FLOW ZERO button momentarily to calibrate the Flow Sensor.

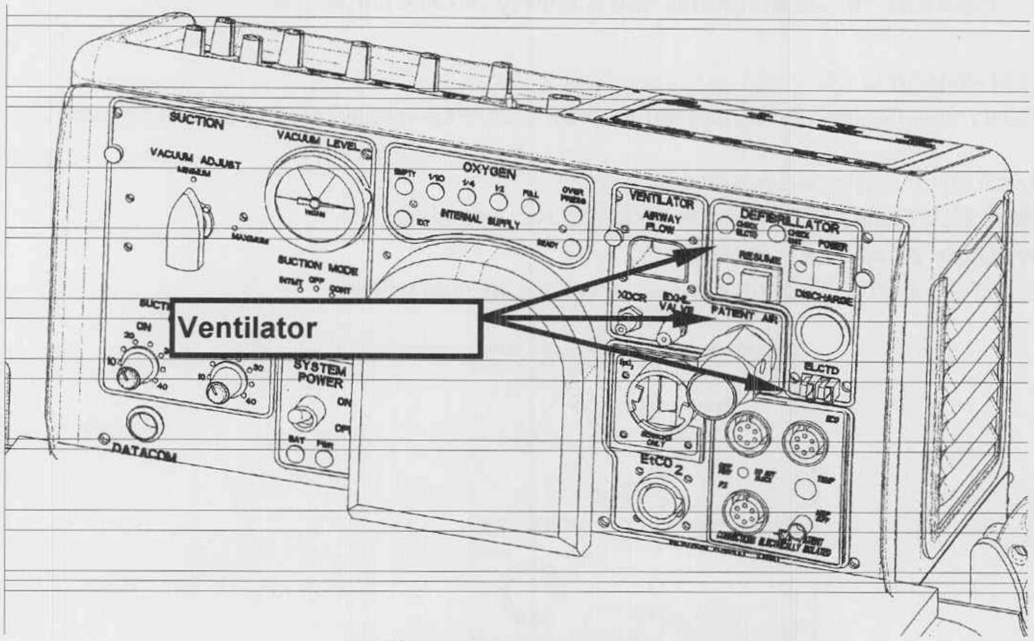


Figure 12-18. Ventilator Connectors

TEST ALL MODES FOR CORRECT OPERATION PRIOR TO PATIENT CONNECTION.

WARNING

FUNCTIONS WHICH ARE DEPENDENT UPON ACCURATE PRESSURE READINGS SHOULD ONLY BE USED IN CONJUNCTION WITH A PROTECTED AIRWAY. THIS WILL PREVENT "LEAKS" FROM DISTORTING PRESSURE SIGNALS. DO NOT USE PRESSURE DEPENDENT FUNCTIONS WITH AN UNPROTECTED AIRWAY. THIS APPLIES PRIMARILY TO USE WITH UNCUFFED ENDOTRACHEAL TUBES, UNCUFFED TRACHEOSTOMY TUBES AND RESUSCITATION MASKS WHERE THE FACE-TO-MASK-SEAL INTEGRITY IS FREQUENTLY AND TYPICALLY COMPROMISED.

The ventilator can operate in the following modes:

- ASSIST-CONTROL VENTILATION with or without PEEP, with or without SIGH
- ASSIST-CONTROL VENTILATION with or without PEEP, with or without PRESSURE PLATEAU
- SYNCHRONIZED INTERMITTENT MANDATORY VENTILATION with or without PEEP, with or without SIGH
- SYNCHRONIZED INTERMITTENT MANDATORY VENTILATION with or without PEEP, with or without PRESSURE PLATEAU
- CONTINUOUS POSITIVE AIRWAY PRESSURE with or without PEEP
- CONTROL VENTILATION (apnea backup of ACV, SIMV, and CPAP)
- CONTROL VENTILATION (backup ventilator)

ACV, SIMV, and CPAP ventilations are continuously monitored. Should apnea occur in one of these modes, the Ventilator's microprocessor will activate applicable alarms and initiate control ventilations.

NOTE

Control panel settings may be adjusted at any time. In normal use, adjustments are typically made immediately following SELF-CHECK, however, the 1:2 I:E RATIO and extents for FIO_2 and pressure alarms may be preset. Some high demand control settings at ventilator startup may cause the ventilator to trigger failure alarms. Always set the ventilator to moderate settings at startup.

NOTE

- After SELF-CHECK is completed, ventilation cycling begins automatically. The INSPIRATION/EXHALATION Indicator will toggle accordingly during the inspiratory and expiratory cycles of each ventilation.
- When cycling begins, the DISCONNECT alarm will activate. This alarm will remain active until the disposable ventilator circuit is connected to the patient and the pressure transducer detects a pressure rise during the next ventilator generated breath, or the ALARM MUTE/CANCEL Pushbutton Switch is pressed.

If the ventilator fails SELF-CHECK, a VENTILATOR FAIL Alarm will occur. Return the MODE Selector Switch to its OFF position and then repeat this procedure. If SELF-CHECK fails again, contact IMS support– DO NOT ATTEMPT PATIENT USE.

12.4.9 Oxygen

1. Remove the footpad.
2. Observe the oxygen pressure is 3000 psi. If less than 3000 psi, replace the oxygen bottle (Section 12.5.7).
3. Replace the footpad.
4. Make sure the *SYSTEM POWER* switch is *ON*.
5. Turn the Oxygen Switch located on the head fairing to the ON position (Figure 12-19).
6. Observe the INTERNAL OXYGEN SUPPLY on the Operator/Patient Interface Panel. Verify ¼, ½, ¾, and FULL LEDs are illuminated. If FULL is not illuminated, replace the oxygen bottle (Section 12.5.7).
7. Turn the Oxygen Switch located on the head fairing to the OFF position (Figure 12-19).

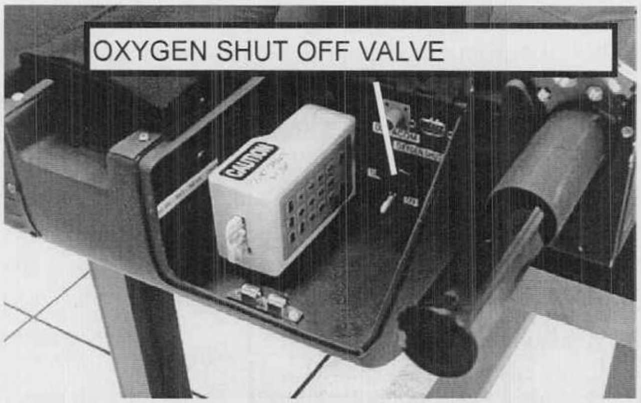


Figure 12-19. Oxygen Switch

12.4.10 Electrical Power

The LSTAT system is powered by Internal Batteries or an External Power source. The two-position *SYSTEM POWER* toggle switch located on the Operator/Patient Interface Panel controls power to the LSTAT. When power is applied the green *PWR* LED is illuminated. If internal power is used then the amber *BAT* LED is also illuminated. The SYSTEM POWER control also provides power to the Data Display and Logging System, and Environmental Control System. The medical subsystems are controlled by separate power controls.

Internal Power

1. Press the BATTERY *CHECK* button on the Indicator Panel.
2. Observe BATTERY LEDs indicate a usable charge level.
3. Toggle the *SYSTEM POWER* switch to *ON*.
4. Observe *PWR* LED is illuminated.
5. Observe the BAT LED is illuminated.

External Power

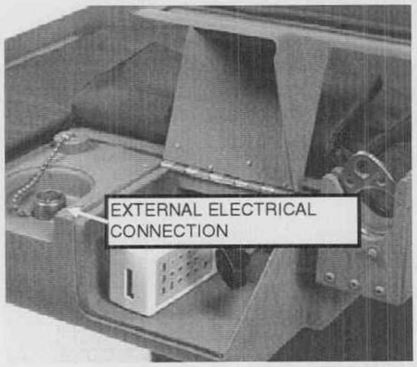


Figure 12-20. External Electrical Connection

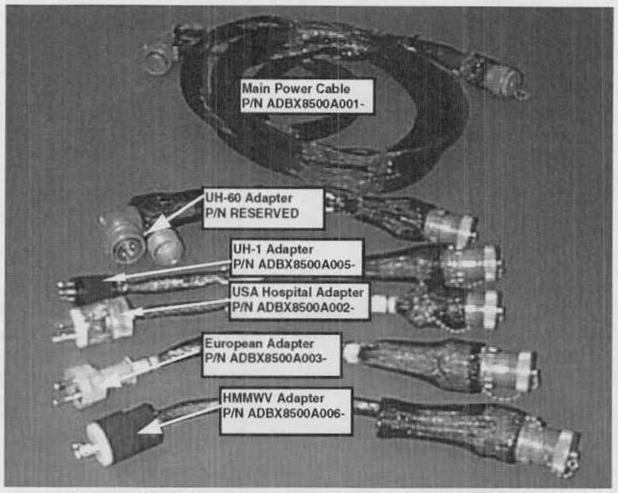


Figure 12-21. Electrical Cable and Adapters

1. Verify the *SYSTEM POWER* switch is *OFF*.
2. Connect the adapter for the available power source to the power cable (Figure 12-21).
3. Connect the power cable to the LSTAT Main Power Connector (Figure 12-20).
4. Connect the external power adapter into the external power source.
5. Toggle the *SYSTEM POWER* switch to *ON*.
6. Observe *PWR* LED is illuminated.
7. Toggle *TRICKLE CHARGE* switch to *ON*.

NOTE

- LSTAT cannot Tickle Charge when using external DC power if the *SYSTEM POWER* switch is *OFF*.
- Internal batteries will charge with the *TRICKLE CHARGE* switch *ON* or *OFF* when *SYSTEM POWER* is *ON* and connected to external AC power.
- The BATTERY *CHG* LED on the Indicator Panel will illuminate when using external AC power.

12.4.11 Environmental Control

The Environmental Control system provides internal ventilation for LSTAT and is automatically activated when *SYSTEM POWER* is switched *ON*.

1. Observe the green FAN light on the Indicator Panel is on.
2. Observe the OVERTEMP light is not on.
3. Feel for vibration caused by the fan motor.

12.4.12 Secondary Display

1. Connect the Secondary Display Monitor to the LSTAT (Section 11.3.1).
2. Power up the Secondary Display Monitor and make sure Secondary Display software is running.
3. Examine computer screen pages for any obvious errors, defects, and old data. Note problems, correct as necessary within operator capabilities.
4. Ensure that the Stylus is functional. Replace the AAAA alkaline battery if necessary and/or replace the stylus tip if it is worn. This will be exhibited by loss of stylus functionality or erratic function.
5. Re-check that screens are ready for next use.
6. Power off the Secondary Display Monitor and disconnect it from the LSTAT.

7. Power off the LSTAT.

12.5 Scheduled Maintenance/Service

12.5.1 Physiological Monitor

The physiological monitor should be serviced semiannually, every 3 years and every 5,000 hours. Table 12-3 shows the recommended service intervals.

Table 12-3. Recommended Physiological Monitor Service Intervals

Recommended Interval	Service Action
Semiannually	Complete Functional Verification and Safety Check
Minimum every 3 years	Replace lithium battery Replace NIBP air filter Replace NIPB tubing
Every 5,000 hours of operation or when screen becomes difficult to view.	Replace LCD backlight

12.5.2 I-Stat

Software Update

The Clinical Analyzer has a periodic software upgrade requirement. The clinical analyzer diagnostics will alert the user to this requirement.

When this occurs perform the following:

1. Remove the PCA from service and forward to the next level of maintenance to be upgraded.
2. Determine whether or not the DDLS portion of the LSTAT will require updating in order to recognize the updated PCA. Check with the next higher level of maintenance for this determination.
3. Upon return from the next level of maintenance place the PCA in its cradle in the LSTAT.

NOTE

- Whenever a software upgrade to the PCA is required the DDLS portion of the LSTAT must also be checked to determine if the LSTAT will also require updating. If the LSTAT requires updating and is not then it will not recognize the PCA.
- If PCA use is imminent ensure that the PCA is/has been tested with the Electronic Simulator.

12.5.3 Fluid/Drug Infusion

The Fluid/Drug Infusion System is designed for reliable, long-term operation. However, annual preventive maintenance is required to maintain optimum performance and to detect the need for repair or adjustment. Such maintenance should be completed in the order presented in sections A through G that follow.

CAUTION

Inspection should be performed before cleaning to ensure there is no damage that could cause fluid to enter the case interior.

NOTE

*The instrument should be cleaned (*Section 12.2.4*) before calibration to remove dirt, dried solutions, and debris from the sensors.*

WARNING

Functional tests should be performed at the completion of the annual maintenance check to insure that the instrument performance is within the required specifications before being returned to patient use.

A. Inspection

Certain defects can be determined by inspecting the instrument. Check for the following defects.

1. AC Adapter

- Housing is intact, free of cracks, and the side of the case is not bulged or dimpled.
- Cable insulation is intact and not frayed or cut.
- Instrument connector shell is intact and pins are not damaged.

2. Loose Parts

- Shake instrument to ensure that there are no loose internal parts.

3. Main Housing

- There are no significant cosmetic defects.
- Labels are intact.
- Main housing is intact and free from cracks.
- Audio/connector PCBA dust covers are intact and free of cracks.
- Battery pack is flush with top of case and sealing gasket is not visible.
- Main housing is flush with chassis and sealing gasket is not visible.

4. Main Housing

- Keypad is not damaged or delaminated.
- Text on LCD is aligned evenly with keypad window (i.e. LCD is not crooked).
- LCD is free of cracks.

5. Lower Housing

- Housing is securely attached.
- Housing is intact and free of cracks.
- Lower housing clips are intact.
- Chassis mounts are intact.

6. Mechanisms and Sensors

First, clamp instrument to a table, remove lower housing, and rotate instrument so that the pumping mechanisms are on top. Ensure the following:

- Air-in-line sensor modules are attached securely.
- Air-in-line sensor tubing recess is thoroughly cleaned.
- Slide links are clean and move freely.
- Pump latch assemblies are intact and springs seated properly.
- Pump latch assemblies open and close with a firm snap.
- Pump shaft seals are seated.
- Valve actuator tips are not damaged.
- Valve actuator seals are not damaged and are seated properly.
- Pressure transducers are seated and their tape covers intact.

B. Cleaning

If inspection indicates cleaning is needed, refer to Section 12.2.4. Always clean before completing the remaining preventive maintenance procedures. This ensures that the sensors are clean and dry before calibration.

C. Retrieving the Event Log

Refer to the FMS Directions For Use manual for complete instructions.

1. Attach the RS-232 communications cable from the PC to the instrument COMM port.
2. Sign on to FMS. Select the Event Log command from the Main Menu, and then store the Event Log to a file.

3. View or print the event log. Inspect Event Log for watchdogs, faults or other system errors.

D. Checking Memory Backup Battery

A lithium primary cell backs up memory and powers the Real-Time Clock (RTC) when the instrument is turned off. This battery should be replaced every five years. The installation date is displayed on the Battery History Log page (date is in the top line on the right-hand side). The Battery History Log is accessed by the BATLOG softkey. The BATLOG softkey is displayed by pressing the MoreOptions key while on the Standard Display page (software version 3.2 and higher).

NOTE: *Memory contents will be lost during replacement of the lithium backup battery, so this step should be performed after retrieving the Event Log and before calibrating the instrument.*

E. Verifying Proper Software Version, Serial Number, and Customized Settings

Verify that the software version installed in the instrument is appropriate by viewing either the Instrument Information page during power-up, or the Model 2860 I.D. page and Model 2863 Configuration pages 4 and 5 that is available when the MORE OPTIONS key is used.

Determine the serial number stored in instrument memory. This can be read from either the instrument Information page or the I.D. page. If the serial number is not the same as the number on the rear label of the instrument, use FMS to enter the correct number (refer to FMS manual for details).

Verify that the instrument settings that IMS has chosen to customize are configured properly. Refer to the FMS Manual.

F. Calibration

Annual calibration is recommended to account for any wear or drift in the sensor systems. These sensor systems include cassette/latch, patient-side occlusion, and fluid-side occlusion. Be sure that the sensors are clean and dry before recalibrating.

G. Functional Tests

Functional tests are recommended to verify that the instrument is performing within specifications. Refer to Section 12.4.5 for detailed procedures. These functional tests include the following.

- Power-up
- Cassette/latch sensor
- Patient-side occlusion detection
- Fluid-side occlusion detection
- Air-in-line detection
- Battery operating time
- Volume accuracy
- Watchdog audio (software versions 3.3 and higher)
  - Communications

12.5.4 Defibrillator

The Defibrillator performs a self-test each time defibrillator power is turned on and turned off. The self-test verifies the integrity of key components but does not eliminate the need for regular servicing. The following diagnostic test will force error conditions to verify that the Defibrillator can properly diagnose error conditions and is ready for re-use/re-issue.

> NOTE
> The defibrillator electrodes must be connected to the defibrillator connector when not in use.

1. Perform at least one rescue or simulated rescue attempt at least once a year to maintain capacitors in working order.
2. Replace electrode package with a new package, if it is past its expiration date.

12.5.5 Suction

Preventative Maintenance inspections (PMI) should be made as follows:

Usage	Frequency
Less than 50 hrs./Month	Bi-monthly
Greater than 100 hrs./Month	Monthly

The following checks are required at the **next higher level of maintenance.**

Maximum Flow

Measure the maximum free airflow with a flow meter. Perform this test with the collection canister in place. Do not use a collection canister that has a filter attached to it. Filters cause restrictions resulting in reduced free airflow.

> NOTE
>
> Use a connecting hose that has an internal diameter properly sized to the collection canister fitting.

1. Connect flow meter to patient fitting on collection canister using a small length of connecting hose.
2. Set the Vacuum Adjust valve to Maximum.
3. The suction unit should produce a minimum of 30 (+/- 10%) liters per minute free airflow.
4. If the unit fails this check, contact IMS support.

Rate of vacuum rise (Pump down)

This check records the amount of time it takes to reach 300mm (11.8") Hg when the patient fitting is occluded.

1. Set up collection canister without a filter.
2. Set the Vacuum Adjust Valve to Maximum.
3. Set Suction Mode switch to CONT (Continuous)
4. The unit should reach 300mm Hg within 4 seconds.
5. If the unit fails the check, then contact IMS support.

Maximum Vacuum

This check records the maximum attainable vacuum.

1. Set up the collection canister without a filter.
2. Set the Vacuum Adjust Valve to Maximum.
3. Set Suction Mode switch to CONT (Continuous).
4. 550mm (21.6") Hg of vacuum should be observed.
5. If lower readings are noted then check for air leaks in the collection canister, hoses and around fittings.
6. If this condition persists, contact IMS support.

Maximum Intermittent Vacuum

This check records the maximum intermittent vacuum.

1. Set up the collection canister without a filter.
2. Set the Vacuum Adjust Valve to Maximum.
3. Set the Suction Mode knob to INTMT (Intermittent).
4. No more than 200 mmHg of vacuum should be observed.
5. If higher readings are observed, then the unit must be taken out of service and recalibrated.

Vacuum Gauge Accuracy.

This check compares readings between a test gauge and the unit gauge.

1. Compare vacuum readings at various settings.
2. Readings between unit gauge and test gauge should be with 10% of each other.
3. If Gauge fails this check then the gauge will have to be removed and replaced, necessitating removal of the LSTAT from service.

12.5.6 Ventilator

Calibration measurements should be made each year unless significant usage warrants a shorter period between turnaround actions. A complete calibration check should be made following each 2000 hours of cumulative use or 12 month period. Following 6 months of continuous storage or non-use, the ventilator should be examined and operationally tested before patient use attempted.

Recommended maintenance checks:

1. Verify integrity of all hose and tubing connections.
2. Check all control panel settings.
3. Verify that compressor inlet filter is not clogged or dirty.
4. Check for operating power.
5. Verify successful SELF-CHECK
6. Perform TRANSDUCER CALIBRATION, if required.

12.5.7 Oxygen

Oxygen Bottle Removal

1. Check to make sure no ignition sources are present.
2. Turn the Oxygen Switch located on the head fairing to the OFF position.
3. Remove patient cushion from foot compartment panel.
4. Loosen attaching hardware and remove foot compartment panel.
5. Loosen the nut that fastens the CGA-540 tee assembly to the bottle/shut-off assembly (Figure 12-22).

CAUTION

To preclude damage to surrounding hardware and the Detachment Nut ensure that the oxygen wrenches supplied with the Accessory Bag (Aluminum 1" Hex – Red and 1 1/8" Flat Wrench) are used when loosening the nut.

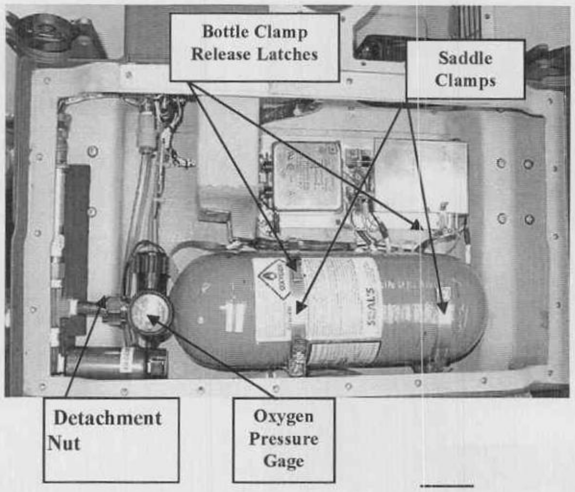


Figure 12-22. Oxygen Layout Showing Detachment Nut

6. Release the bottle clamp release latches on the saddle clamps holding oxygen bottle in place.
7. Remove the Oxygen cylinder from the saddle clamps in the foot compartment.

Oxygen Bottle Replacement

1. Place the bottle/Shut-Off Assembly in the bottle saddle located in the LSTAT foot compartment such that the CGA-540 fitting on the top of the Shut-Off Valve lines up with the bottom of the CGA-540 Med Tee Coupling. Ensure the pressure gauge is facing up (Figure 12-22).
2. Locate the two bottle clamp release latches and ensure they are both to one side of the oxygen bottle. Do not fasten at this time.
3. Turn the detachment nut of the Med Tee Coupling clockwise and hand tighten.
4. Fasten the two bottle clamp release latches that will hold the bottle in place. Tighten the two hex head screws on the saddle clamps, as necessary.
5. Verify that the cylinder has a full charge (3,000 psi) by observing the mechanical gauge on the bottle assembly.
6. Attach Foot compartment panel to LSTAT.
7. Attach the patient cushion to foot compartment panel.

CAUTION

- Avoid contaminating any of the components that will be exposed to oxygen (e.g. dirt, dust, solvents or any other foreign matter).
- To preclude damage to surrounding hardware and the Detachment Nut ensure the Aluminum 1" Hex – Red and 1 1/8" Flat Wrench are used when tightening the nut.
- Do not over tighten nuts as nut is over an o-ring seal. Over tightening will require the use of a back up wrench the next time the bottle is removed.

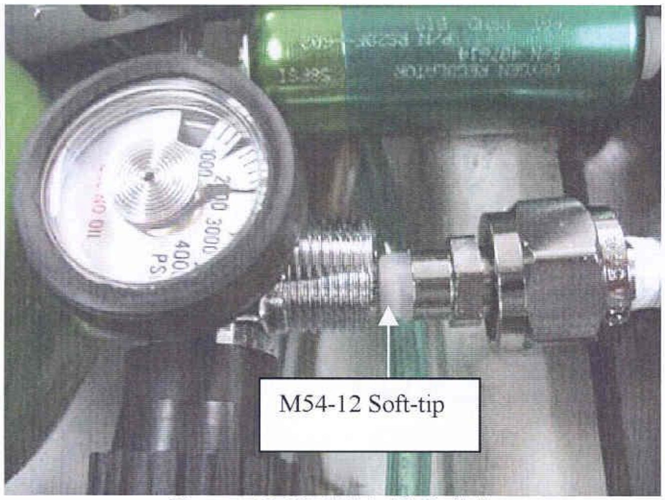


Figure 12-23 M54-12 Soft-tip

NOTE

If a complete seal is not made, check the M54-12 teflon soft-tip (Figure 12-23) for stress cracks and replace it with a spare from the per-patient disposables pack. To remove the teflon soft-tip, pull gently straight out and push the new one on.

12.5.8 Electrical Power

12.5.9 Environmental Control

12.6 TROUBLESHOOTING

12.6.1 LSTAT System

Before replacing the LSTAT check the following:

1. The main power cord is connected.
2. The external power source is live and is the correct type of power for the LSTAT.
3. Operationally check all subsystems.

12.6.2 Electrical Power

Before removing and replacing the LSTAT check the following:

1. There is sufficient power to operate the LSTAT.
2. Check circuit breakers in foot compartment. If "popped", push in to reset.
3. Recycle power to the LSTAT.
4. Check for sufficient battery power.

12.6.3 Environmental Control

Before removing and replacing the LSTAT for Environmental Control Subsystem failures check the following:

1. The LSTAT has sufficient power to operate.
2. Check for diminished airflow.
3. Check for damaged, dirty or clogged filters. Clean or replace as necessary.

12.6.4 Physiological Monitor

Before removing and the replacing the physiological monitor check the following:

1. The LSTAT has sufficient power to operate.
2. Recycle power to the physiological monitor.
3. Check the window for status or error messages.

12.6.5 Suction

Before removing and replacing the Suction Unit check the following:

1. The LSTAT has sufficient power to operate.
2. Check for vacuum at the inlet of each item.
3. Trace backward through the system, i.e.: vacuum from the collection canister filter assembly to the Vacuum inlet fitting.
4. For filters: Trace the Vacuum backward from the collection canister to the filter, then vacuum from the filter to the Vacuum inlet fitting.
5. Check tubing for crimps and cuts.
6. Check wiring for frays.
7. Ensure collection canisters seal properly.
8. Ensure overflow shut-off valves do not stick.

12.6.6 Defibrillator

Before removing and replacing the Defibrillator unit check the following:

1. The LSTAT has sufficient power to operate.
2. Recycle power to the Defibrillator (CHAPTER 6).
3. Check expiration date on Electrodes and replace as necessary.

12.6.7 Fluid/Drug Infusion

Before removing and replacing the Infusion Pump check the following:

1. The LSTAT has sufficient power to operate.
2. Recycle power to the pump.
3. Proper procedures have been followed in setting up and operating the pumps.

12.6.8 Ventilator

Before removing and replacing the LSTAT with the Ventilator check the following:

1. The LSTAT has sufficient power to operate.
2. Verify successful SELF-CHECK and perform TRANSDUCER CALIBRATION, if required.
3. The Patient Circuit and Sensors are functional.
4. The external air hose, fittings and external air source are functional.
5. Verify integrity of all hose and tubing connections.
6. Check all control panel settings.
7. Verify that compressor inlet filter is not clogged or dirty.
8. Check that Vent Drain Hole in foot portion of stretcher foot well is not clogged.

12.6.9 Oxygen

Before removing and replacing the Oxygen bottle check the following:

1. Ensure the LSTAT electrical system is on and functioning.
2. Double check the Oxygen Supply lights for any lights out conditions.
3. Check the oxygen pressure gauge through the port in the Foot compartment for pressure information.

12.6.10 Clinical Analyzer

Before removing and replacing the Portable Clinical Analyzer check the following:

1. The LSTAT has sufficient power to operate.
2. Corrective actions from error messages from display screen have been followed properly.
3. Batteries are O.K.
4. The blood analyzer is current and its software has not expired
5. Correct cartridges are being used properly.
6. The IR Link/Cradle is functioning.

12.6.11 Secondary Display

Before removing and replacing the Secondary Display check the following:

1. The LSTAT has sufficient power to operate.
2. The Secondary Display is properly connected to the LSTAT.
3. The Secondary Display Stylus battery and tip are functional.

12.7 Preparation for Shipment and Storage

WARNING

The Propaq battery may be damaged by storage longer than 3 months.

12.7.1 Shipping and Short-term Storage (0-6 months)

1. Secure all components mounted on the LSTAT.
2. Verify *SYSTEM POWER* switch is *OFF*.
3. Press BATTERY *CHECK* and verify batteries are fully charged.
4. Pull all breakers in the foot compartment.
5. Remove footpad and verify oxygen bottle pressure is 3000 psi. Replace Oxygen bottle if necessary (Section 12.5.7).
6. Verify *Oxygen Switch* is turned off on the head fairing.
7. Clean, disinfect and dry LSTAT (see cleaning instructions in Section 12.2.1).
8. Remove/store loose items (screws, devices, covers, and subsystems).
9. Place LSTAT in its shipping container.

12.7.2 Long-term Storage (6 months or more)

In addition to short-term storage preparation, long-term storage requires the removal of the oxygen bottle.

1. Remove the foot pad and foot compartment panel
2. Disconnect the oxygen bottle and remove from LSTAT (Section 12.5.7).
3. Route the oxygen bottle to a suitable storage site.
4. Replace the foot compartment panel and footpad.
5. Place LSTAT into its shipping container.

12.8 PREVENTIVE MAINTENANCE

Preventive Maintenance is required on a scheduled basis for the LSTAT. Refer to Appendix E for a listing of the types of tasks for each subsystem, their frequency and at what level of maintenance these tasks are performed.

12.9 CALIBRATION

The LSTAT has a requirement for its subsystems to be calibrated on a scheduled basis. Refer to Appendix E for a list of the tasks to be performed for each subsystem, their frequency and the level of maintenance that is required to be performed.

APPENDIX A Support Equipment Listing

NOMENCLATURE	PART NO. /TYPE DESIGNATION	CAGE
EXTERNAL POWER SOURCE	105-120 VAC, 60 Hz 108-118/200 VAC, 3 Phase 400 Hz ±7 Hz 210-220 VAC 50 Hz 25-30 VDC	N/A
ELECTRONIC SIMULATOR	130200	
SCREWDRIVER	Phillips #2	
SCREWDRIVER	Flat Tip #2	
WRENCH	Adjustable	
FLASHLIGHT	Common/Standard Issue	
OXYGEN WRENCHES	1" and 1 1/8" Craftsman or Equivalent	

APPENDIX B SPARE PARTS LIST

ITEM	P/N	QTY	REV	TITLE	ALTERNATES
1	008-0108-00	1		Pulse Oximeter Extension Cable	
2	008-0130-01	1		Mainstream Capnography Sensor & Airway Adapter Set	
3	008-0150-00	2		Velcro Cable Tie Wraps, 1" x 6", Black	
4	008-0234-00	1		Temp Sensor Cable	
5	008-0238-00	1		Non-Invasive BP Conn/Hose	
6	008-0291-13	1		Non-Invasive Blood Pressure Cuff, Adult Small, Reusable	
7	008-0291-14	0		Non-Invasive BP Cuff, Adult, Standard, Bladderless	Alternate for 008-0628-00
8	008-0291-16	1		Non-Invasive Blood Pressure Cuff, Thigh, Reusable	
9	008-0315-00	1		ECG leads and cable	
10	008-0628-00	1		Non-Invasive Blood Pressure Cuff, Adult, Standard, Reusable	Or Alternate
11	008-0629-00	1		Non-Invasive Blood Pressure Cuff, Adult Large, Reusable	
12	130100	1		Electronic Simulator, I-STAT	
13	465-0012-00	2		Filter, Foam Inlet, Ventilator	
14	490-0005-00	1		Leaf Valve, Ventilator	
15	704-0326-09	1		Collection Canister, Suction, Secondary	
16	A6MC2	2		Male Connector 3/8" Stem x 1/8" NPT	
17	ADBX3400A002	1		Assembly, Auxiliary Suction Bottle Holder	
18	ADBX5000A001	1	B	Assembly, IV Pole	
19	ADBX5100A002	1	A	Modification, IVAC Mounting Clamp, IV Infusion Subsystem	

ITEM	P/N	QTY	REV	TITLE	ALTERNATES
20	ADBX8500A001-001	1	A	Cable, Power, Main, 15 ft long	
21	ADBX8500A002	1		Cable, Adapter, Power, 115VAC 60Hz	
22	ADBXA600A045	1		Cable, Secondary Display Power/Data	
23	ADBXB300A002	0		Secondary Display Assembly (1000)	Alternative to ADBXB300A006
24	ADBXB300A005	0		Secondary Display Assembly (1200)	Alternative to ADBXB300A006
25	ADBXB300A006	1		Secondary Display Assembly (2300)	Or Alternate
26	ADBXC100A002	1		Oxygen Bypass Assembly	
27	ADBXC112D001	1	A	Placard, Oxygen Hookup	
28	ADBXC113D001	1	A	Placard, Ventilator Circuit	
29	ADBXC114D001	1	A	Placard, Accessory Bag Contents	
30	ADBXC115D001	5		Cord, Cable Tie - Dacron - 1/8" Dia. 24" length	
31	ALBX0300J003	1		User Manual, LSTAT 9602B	
32	BATTERY AAAA, 2-Pack	1		Battery, AAAA, 1.5V, Alkaline, 2-Pack	
33	C165-1020	1		Test Lung, Adult, 1 Liter, Heavy Duty	
34	DS-100A	0		SpO2 Durasensor Adult Digit O2 Transducer	Alternate to DS-100A-1
35	DS-100A-1	1		SpO2 Durasensor Adult Digit O2 Transducer	Or Alternate
36	G95586	2		Restraints	
37	L522FP	2		Battery, Lithium, 9.0 Volt	
38	LSTAT-9999	1		Accessory Bag, with Pouches, LSTAT 9602	
39	LSTAT1P-9999	5		Pouch, Large, Accessory Bag, LSTAT 9602	
40	MHA-16C-120-B3-B3	1		Hose and Fittings, External Air, Yellow	

ITEM	P/N	QTY	REV	TITLE	ALTERNATES
41	MHA-24C-120-B1-B1	1		Hose and Fittings, External Oxygen, Green	
42	MX4805	1		C-Fusor	
43	MX980-14	2		IBP Cable	
44	PI 081200-S	2		Tube Plug, Acetal	
45	PI 291210-S	2		Elbow, Acetal	
46	PP-500-10D	1		Wrench - Aluminum 1" Hex - Red	
47	Wrench, CGA-540	1		Wrench, Oxygen, CGA-540, 1 1/8 inch	

APPENDIX C Customer Complaint Form

1. DATE:	2. TIME:	PERSON & TITLE FILLING OUT FORM:
4. NAME OF COMPLAINANT:		5. PHONE NO.
6. COMPLAINANT ADDRESS:		
COMPLAINT RECEIVED BY: ☐ Visit ☐ Phone ☐ Letter ☐ Sales ☐ Credit Memo ☐ Other		
8. COMPLAINT ABOUT		
☐ Sterility		
☐ Particulate Matter Type	Location	
☐ Defect		
☐ Packaging		
☐ Labeling		
☐ Patient Death		
☐ Patient Injury		
☐ Product Malfunction		
☐ Other (specify)		
9. Comments/Description of Event (*DESCRIBE TO BEST ABILITY, WHAT IS WRONG, HOW AND WHY, CIRCUMSTANCES PRIOR TO DIFFICULTY, DESCRIPTION OF DIFFICULTY, CAUSE, ACTION TAKEN, INCLUDING DISPOSITION, RECOMMENDATIONS. ATTACH COPIES OF SUPPORTING DOCUMENTS. CONTINUE ON SEPARATE SHEET NECESSARY*)		

LSTAT COMPLAINT FORM CF01

LSTAT COMPLAINT FORM INSTRUCTIONS

1. Submit this form when registering a complaint involving the LSTAT function.
2. A 24/7 pager is available at (888) 266-2061
3. This form may be e-mailed to Integrated Medical Systems at support@lstat.com or mailed to:

Integrated Medical Systems, Inc.
.1984 Obispo Avenue
Signal Hill, CA 90804

4. Fill out the form as applicable: (Enter N/A for any blocks that are not applicable).

Block 1: DATE. Enter the date of the incident.

Block 2: TIME. Enter the time of the incident.

Block 3: PERSON & TITLE FILLING OUT FORM. Enter the name of the person actually filling out the form and job position/description

Block 4: NAME OF COMPLAINANT. Enter the name of the person that the complaint is from.

Block 5: PHONE NUMBER. Enter the phone number of the person or organization filing the complaint.

Block 6: ADDRESS OF COMPLAINANT. Enter the address of the person or organization filing the complaint.

Block 7: COMPLAINT RECEIVED. Check the block that most accurately typifies how the complaint arrived.

Block 8: COMPLAINT ABOUT. Check the box that most accurately reflects the complaint.

B*lock 9*: COMMENTS/DESCRIPTION of EVENT. Provide a written description of the events leading up to and a description of the complaint.

APPENDIX D Accessories

PART NUMBER	DESCRIPTION	QTY./ BAG	DISPOSABLE (D) REUSABLE (R)	INTENDED USE/PURPOSE
LSTAT-9999	ACCESSORY BAG	1	R	CONTAINS LSTAT ACCESSORIES.
LSTAT1P-9999	POUCH, LGE ACCESSORY BAG, LSTAT 9602B	5	R	POUCHES FOR LSTAT ACCESSORIES
	PHYSIOLOGICAL MONITORING SUBSYSTEM			
008-0150-00	VELCRO CABLE WRAPS	2	R	TIES OFF CABLES AND TUBING.
008-0315-00	ECG LEAD	1	R	CONNECTS TO physiological monitor ECG ELECTRODES.
1700-003	ECG ELECTRODES	1	D	ATTACHED TO PATIENT WHEN USING physiological monitor ECG.
MX9504CSTT	CLOSED BLOOD SAMPLE SET	2	D	USED FOR BLOOD SAMPLING AND INVASIVE PRESSURE MEASUREMENT.
MX4805	C-FUSOR	1	R	USED WITH CLOSED BLOOD SAMPLE FOR INVASIVE PRESSURE MEASUREMENT.
MX98014	IBP CABLE	2	R	CONNECTS TO physiological monitor IBP OUTLET AND THE CLOSED BLOOD SAMPLE SET.
008-0291-13	NON-INVASIVE BP CUFF-sm	1	R	FOR NON-INVASIVE BLOOD PRESSURE USE
008-0291-14	NON-INVASIVE BP CUFF-std	0	R	FOR NON-INVASIVE BLOOD PRESSURE USE O ALT for 008-0628-00
008-0291-15	NON-INVASIVE BP CUFF-lge	0	R	FOR NON-INVASIVE BLOOD PRESSURE USE O ALT for 008-0629-00
008-0628-00	NON-INVASIVE BP CUFF-std	1	R	FOR NON-INVASIVE BLOOD PRESSURE USE N ALT for 008-0291-14

PART NUMBER	DESCRIPTION	QTY./ BAG	DISPOSABLE (D) REUSABLE (R)	INTENDED USE/PURPOSE
008-0629-00	NON-INVASIVE BP CUFF-large	1	R	FOR NON-INVASIVE BLOOD PRESSURE USE N ALT for 008-0291-15
008-0291-16	NON-INVASIVE BP CUFF-thigh	1	R	FOR NON-INVASIVE BLOOD PRESSURE USE
008-0238-00	NON-INVASIVE BP CONN/HOSE	1	R	CONNECTS TO BP CUFFS.
008-0234-00	TEMP INTERCONNECT CABLE (4940)	1	R	CONNECTS THE physiological monitor TO THE TEMP SENSOR.
008-0228-00	TEMP SENSOR (4499E)	1	D	PATIENT TEMPERATURE MEASUREMENT.
008-0227-00	TEMP PROBE YSI 400&700 SERIES (4491E)	1	D	ALTERNATIVE PATIENT TEMPERATURE MEASUREMENT.
008-0236-00	TEMP HEART STICK-ONS (4012)	2	D	USED TO ATTACH SKIN TEMPERATURE MEASUREMENT SENSOR.
008-0130-01 (aka 008-0502-00)	MAINSTREAM CO_2 SENSOR AND AIRWAY ADAPTER SET	1	R	MEASURES INSPIRED AND EXPIRED CO_2 IN THE AIRWAY.
008-0132-XX	CO_2 ADULT/PEDIATRIC AIRWAY ADAPTERS	1	D	USED WITH CO_2 SENSOR.
DS-100A	SpO_2 DURASENSOR ADULT DIGIT O_2 TRANSDUCER	0	R	MEASURES BLOOD OXYGENATION NON-INVASIVELY. Replaced by DS-100A-1
DS-100A-1	SpO_2 DURASENSOR ADULT DIGIT O_2 TRANSDUCER	1	R	MEASURES BLOOD OXYGENATION NON-INVASIVELY. Replaced DS-100A
D-25L	SpO_2 OXYSENSOR II ADULT DIGIT O_2 TRANSDUCER WITH 36" CABLE	3	D	MEASURES BLOOD OXYGENATION NON-INVASIVELY.
008-0108-00 (aka 010-0051-00)	SpO_2 8 FOOTEXTENSION CABLE	1	R	ATTACHES TO THE SpO_2 SENSOR.
7222	FLOW SENSOR & CONNECTOR	1	D	USED TO MEASURE AIRWAY FLOW AND VOLUME.
	SUCTION SUBSYSTEM			

PART NUMBER	DESCRIPTION	QTY./ BAG	DISPOSABLE (D) REUSABLE (R)	INTENDED USE/PURPOSE
704-0326-09	SECONDARY COLLECTION CANISTER	1	R	FOR ADDITIONAL FLUID CAPTURE.
ADBX3400A002	AUX. SUCTION BOTTLE HOLDER	1	R	ATTACHES TO LSTAT WITH ADDITIONAL CANISTER.
42400	STERILE SUCTION CONNECTING TUBING	1	D	ADDITIONAL SUCTIONING CAPABILITY.
6144400	NPT 1/8 MALE FILTER 50 mm HOUSING	5	D	ATTACHES TO TOP OF CANISTER.
51052	ADAPTER, 15 mm MALE X 22 mm FEMALE, clear	1	D	
299	SUCTION YAN KAUER W/VENT	1	D	USED WITH P/N'S 42400 OR 284711.
PI 291210-S	ELBOW-ACETAL	2	R	INTERFACE BETWEEN CANISTER AND TUBING.
A6MC2-MG	MALE CONNECTOR-ACETAL	2	R	INSTALLED IN CANISTER.
PI 081200-S	TUBE PLUG-ACETAL	2	R	SEALS THE CANISTER WHEN FULL.
303	SUCTION CATHETER w/ PRE-CONNECTED TUBING	1	D	SUCTIONS PATIENT FLUIDS.
T60C	SUCTION CATHETER 14 fr	1	D	PATIENT AIRWAY SUCTION.
	PORTABLE CLINICAL ANALYZER			
L522FP	9 VOLT BATTERY, LITHIUM	2	R	SPARES TO OPERATE ANALYZER.
130100	ELECTRONIC SIMULATOR	1	R	TESTS ANALYZER.
	DEFIBRILLATOR SUBSYSTEM			
9130	ELECTRODES	1	D	ATTACHES TO PATIENT FOR DEFIBRILLATION
	IV FLUIDS AND DRUG ADMINISTRATION SUBSYSTEM			
RS703BLK	RESTRAINTS	2	R	PATIENT HOLD DOWNS.
603890	ADMINISTRATION SET (28265)	3	D	FACILITATES DELIVERY OF IV TO PATIENT.
ADBX5000A001	IV POLES	1	R	ATTACH TO LSTAT, HOLD FLUID BAGS.

PART NUMBER	DESCRIPTION	QTY./ BAG	DISPOSABLE (D) REUSABLE (R)	INTENDED USE/PURPOSE
ADBX5100A002	Mod., IVAC MOUNTING CLAMP	1	R	HOLDS PUMP UPRIGHT WHEN NOT IN DRAWER. ALSO USED WHEN PRIMING.
	VENTILATOR SUBSYSTEM			
C165-1020	TEST LUNG, ADULT, (1 Liter, Heavy Duty)	1	R	
MHA-16C-120-B3-B3	EXTERNAL AIR HOSE AND FITTINGS (YELLOW)	1	R	ATTACHMENT FOR EXTERNAL MEDICAL AIR TO LSTAT.
003764	PATIENT VENTILATOR CIRCUIT (PATIENT BREATHING TUBE CONNECTOR, PATIENT PRESSURE TUBE CONNECTOR, EXHALATION VALVE TUBE-P/N 712865)	1	D	ATTACHES TO PATIENT INTUBATION TUBE AND LSTAT.
51287	PATIENT VENTILATOR CIRCUIT HOSE ADAPTER	1	D	USED WITH FLOW SENSOR AND/ OR CO_2 SENSOR.
490-0005-00	LEAF VALVE	1	R	INSTALLED IN AIRWAY FITTING FOR ANTI-ASPHYXIA.
12519	SUPPLY LINE CLIP	4	D	KEEPS PATIENT CIRCUIT LINES TOGETHER.
5006	VIRAL FILTER	1	D	ANTIBACTERIAL BETWEEN PATIENT AND LSTAT.
465-0012-00	FOAM INLET FILTER	2	R	FILTERS VENTILATOR INLET AIR ON BOTH SIDES OF LSTAT BODY.
	OXYGEN SUBSYSTEM			
MHA-24C-120-B1-B1	EXTERNAL O_2 HOSE & FITTINGS (GREEN)	1	R	EXTERNAL ATTACHMENTS FOR O_2 TO LSTAT.
1059	MASK, OXYGEN	1	D	PATIENT USE.
33102	OXYGEN CONNECTOR W/SWIVEL	1	D	SUBSTITUTE FOR P/N 65401.
M54-12	SEAL, O^2 CYLINDER, SOFT TIP REPLACEMENT	1	D	
PP-500-10D	WRENCH-ALUMINUM 1" HEX-RED	1	R	

PART NUMBER	DESCRIPTION	QTY./ BAG	DISPOSABLE (D) REUSABLE (R)	INTENDED USE/PURPOSE
CGA-540	OXYGEN WRENCH 1 1/8 "	1	R	USED TO REMOVE O_2 BOTTLE FROM LSTAT.
ADBXC100A002	O^2 BYPASS ASSEMBLY	0	R	ALT for ADBXC100A002
ADBXC100A002 Rev A	O^2 BYPASS ASSEMBLY	1	R	
ADBXC100A003	O^2 BYPASS ASSEMBLY	0	R	ALT for ADBXC100A002
ADBXC100A004	O^2 BYPASS ASSEMBLY	0	R	ALT for ADBXC100A002
	ELECTRICAL COMPONENTS			
ADBX8500A001-001	CABLE, POWER MAIN	1	R	PRIMARY CABLE.
ADBX8500A002	CABLE ADAPTER,POWER-USA HOSPITAL (115 VAC, 60 Hz)	1	R	FOR USE IN USA.
	DATA/DISPLAY LOGGING SUBSYSTEM			
ADBXB300A002	SECONDARY DISPLAY ASSEMBLY (1000)	0	R	PATIENT MONITORING AND ANNOTATING. O ALT for ADBXB300A006
ADBXB300A005	SECONDARY DISPLAY ASSEMBLY (1200)	0	R	PATIENT MONITORING AND ANNOTATING. O ALT for ADBXB300A006
ADBXB300A006	SECONDARY DISPLAY ASSEMBLY (2300)	1	R	PATIENT MONITORING AND ANNOTATING.
BATERY-AAAA, 2-PACK	BATTERY, 1.5 volts ALKALINE PACKAGE/2	1	D	BATTERY FOR SECONDARY DISPLAY STYLUS PEN.
ADBXA600A045	CABLE, SECONDARY DISPLAY	1	R	ATTACHES TO LSTAT AND SECONDARY DISPLAY.
4298	HOT PACKS	2	D	ALTERNATE WARMING CAPABILITY FOR SECONDARY DISPLAY.
	MISCELLANEOUS			
G88422	RED BIO HAZARD BAG	1	D	MEDICAL REFUSE

PART NUMBER	DESCRIPTION	QTY./ BAG	DISPOSABLE (D) REUSABLE (R)	INTENDED USE/PURPOSE
ADBXC113D001	VENTILATOR PLACARD	1	R	SHOWS HOW PATIENT CIRCUIT ASSEMBLED
ADBXC112D001	OXYGEN PLACARD	1	R	SHOWS OXYGEN BYPASS CONNECTION.
ADBXC114D001	ACCESSORY BAG CONTENTS	1	R	SUPPLY SUPPORT
ADBXC115D001	CABLE TIECORD-DACRON 1.8" X 24"	5	R	
ALBX0300J002 Rev C	USER MANUAL, LSTAT 9602B	1	R	USER INSTRUCTIONS
9602 ADVISORY NOTICES	9602 ADVISORY NOTICES FOR USER MANUAL	1	R	NOTICES FOR USER MANUAL

APPENDIX E Preventive Maintenance Requirements

The purpose of this chart is to identify the current LSTAT Organizational (O), Intermediate (I) and Depot Level Preventive Maintenance, Tasks, location and task frequency

		Maintenance Level (O, I, or Depot[D])			
SUBSYSTEM	**Preventive Maintenance Task**	**O**	**I**	**D**	**Task Frequency**
Physiological Monitor	Verification and safety check. (Digital Pressure meter & Oscilloscope needed)		X		Semiannually (2x/yr.)
	Check the Calibration of the CO_2 sensor. Replace as necessary		X		Semiannually (2x/yr.)
	Replace the Lithium Battery from Head Fairing.			X	Every 3 years.
	Replace the Lead Acid Battery from Head Fairing.			X	Every 3 years.
	Replace the air filter from Head Fairing.			X	Every 3 years.
	Replace the LCD Back Light from Head Fairing			X	Every 5,000 hr.
Clinical Analyzer	Functional Test i-STAT with Electronic Simulator	X			Daily when in use.
Drug Infusion Pump (DIP)	Functional Test	X			Annually (1 x/year)
	Check main battery using FMS and replace as necessary.			X	Annually (1 x/year)
	Replace the LCD backlight.			X	Every 5,000 hr. (customer recommendation)
	Inspect Pole Clamp	X			Annually (1 x/year)
	Inspect for loose parts	X			Annually (1 x/year)
	Inspect Main Housing	X			Annually (1 x/year)
	Inspect Front Panel	X			Annually (1 x/year)
	Inspect Lower Housing	X			Annually (1 x/year)
	Inspect Mechanism and Sensors	X			Annually (1 x/year)
	Clean as dictated by inspection	X			Annually (1 x/year)
	Retrieve Event Log w/ FMS Save on PC & Print. Inspect for system errors.	X			Annually (1 x/year)
	Check Memory Backup Battery	X			Annually (1 x/year)
	Replace Memory Back-up Battery			X	Every 5 yr.
	Verify proper software version	X			Annually (1 x/year)
Ventilator	Check that all tubing, hoses and fittings are properly connected.			X	Every 12 months or 2,000 hr.

		Maintenance Level (O, I, or Depot[D])			
SUBSYSTEM	**Preventive Maintenance Task**	**O**	**I**	**D**	**Task Frequency**
	Check Manifold screen for debris -Remove cover -Disconnect hoses- -Unscrew manifold fitting -Inspect screen and remove screen -Clean as necessary -Install screen -Install manifold fitting -Reconnect hoses -Verify operator power and check for leaks- -Install cover		X		Semiannually (2x/yr.)
Suction	Replace the Bacterial/Overflow filter contacts	X			Every 150 hr. of use or if discolored, if contacted by aspirate, or airflow is impeded.
	Visually/ inspect all external tubing. (Replace defective tubing)	X			Bi-monthly if less than 50 hr. / month operation or Monthly if usage over 100 hr./ month.
	Visually inspect all external fittings and connectors	X			Bi-monthly if less than 50 hr. / month operation or Monthly if usage over 100 hr./ month.
	Visually /inspect all controls and switches. Check positions to verify correct alignment Record settings of all controls and switches that must be returned to their original positions following inspection check for physical damage, loose mountings and inappropriate motion. If control has fixed limit stops check for proper alignment and positive stopping. Check that each control and switch performs its intended function.	X			Bi-monthly if less than 50 hr. / month operation or Monthly if usage over 100 hr./ month.
	Verify correct operation of the vacuum adjustment control and that it is usable over entire suction range. Perform with vacuum port occluded	X			Bi-monthly if less than 50 hr. / month operation or Monthly if usage over 100 hr./ month.
	Inspect vacuum gauge for cracks and scale visibility.	X			Bi-monthly if less than 50 hr. / month operation or Monthly if usage over 100 hr./ month.

		Maintenance Level (O, I, or Depot[D])			
SUBSYSTEM	**Preventive Maintenance Task**	**O**	**I**	**D**	**Task Frequency**
Suction-cont'd	Check that indicator rests on zero without vacuum applied.	X			Bi-monthly if less than 50 hr. / month operation or Monthly if usage over 100 hr./ month.
	Confirm operation of vacuum pump/motor. Verify delivery of maximum vacuum	X			Bi-monthly if less than 50 hr. / month operation or Monthly if usage over 100 hr./ month.
	Confirm operation of gauge.	X			Bi-monthly if less than 50 hr. / month operation or Monthly if usage over 100 hr./ month.
	Verify that all labeling is intact and legible.	X			Bi-monthly if less than 50 hr. / month operation or Monthly if usage over 100 hr./ month.
	Verify operation of mechanical overflow protection. Liquids must be aspirated into collection canister until protective device is activated. Observe when performing this test so that liquid is not aspirated into pump of overflow mechanism fails. Place a bucket of water on floor adjacent to unit. Connect a short length of hose to patient fitting on collection canister. Turn unit on and suction water into collection canister. Verify activation of overflow protection mechanism.		X		Annually (1x/yr.)
	Measure Maximum flow. Use a flow meter. Perform this test with collection canister in place. DO NOT CONNECT FILTER WHEN PERFORMING THIS TEST. DO NOT PERFORM THIS TEST WITH A DISPOSABLE CANISTER HAVING IT OWN FILTER. FILTERS CAUSE RESTRICTIONS RESULTING IN REDUCED FREE AIR FLOW. Connect flow meter to quick disconnect fitting on the LSTAT Use connecting hose having an inside diameter properly sized to the quick disconnect fitting. Vacuum adjust valve must be set to its maximum vacuum position Look for 27 – 33 lpm free air flow.		X		Annually (1x/yr.)

		Maintenance Level (O, I, or Depot[D])			
SUBSYSTEM	**Preventive Maintenance Task**	**O**	**I**	**D**	**Task Frequency**
Suction-cont'd	Check Rate of vacuum Rise (pumpdown) 1. Put collection canister in place 2. Set the vacuum adjust valve to the maximum vacuum position. 3. Connect to the collection canister. Record the amount of time it takes to reach 300 mmHg when the patient fitting is occluded. Look for the device to reach 300 mmHg within 4 seconds. Do not perform this test with a filter or with a collection canister that has its own integral filter.		X		Annually (1x/yr.)
	Check Vacuum gauge accuracy Using a test gauge, compare the vacuum readings at various vacuum settings. Readings between the unit's vacuum gauge and the test gauge should be within 10%.		X		Annually (1x/yr.)
Oxygen	Check pressure relief valve. -Connect pressurized air to external O2 port. -Increase pressure until relief valve actuates. -Verify actuator pressure is 15 psi ± 10%. **Do not exceed 100 psi when actuating.**		X		Annually (1 x/year)
	Visually inspect tubing and fittings		X		Annually (1x/yr.)
Defibrillator	ATP Defibrillator-perform 1 simulated rescue		X		Annually (1 x/year)
DDLS	Replace Secondary Display battery pack		X		Every 2 years
	Visually check all cables and connectors for uniformity, wear and tear.			X	Annually (1 x/year)
Electrical Power System (EPS)	Check Voltages by running ATP			X	Annually (1 x/year)
	Check battery charge status. Remove and Replace if it does not hold a charge.		X		Annually (1 x/year)
	Check age of battery. Remove and replace if beyond usage time.		X		

		Maintenance Level (O, I, or Depot[D])			
SUBSYSTEM	**Preventive Maintenance Task**	**O**	**I**	**D**	**Task Frequency**
Environmental Control System (ECS)	Check Air and EMI Filters in Head Fairing and replace as necessary	**X**			Every 6 months (semiannually)
	Run ATP to assess functionality		**X**		
	TOTAL TASKS FOR ALL SUBSYSTEMS	**23**	**14**	**10**	**47**

APPENDIX F

Calibration Requirements

			MAINTENANCE LEVEL (ORGANIZATIONAL [O], INTERMEDIATE [I], DEPOT [D])		
Subsystem	**CALIBRATION REQUIREMENT**	**FREQUENCY**	**O**	**I**	**D**
Physiological. Monitor	Calibrate the CO_2 sensor -Barometric Pressure - Adjust EMI	Semiannually, if necessary, based on physiological monitor calibration check			X
Clinical Analyzer (i-STAT)	Update with latest vendor software.	Approx. every 90 days		X	
Infusion Pump	Calibrate using Field Maintenance Software (FMS).	Annually		X	
Ventilator	Calibrate Novametrix Flow Sensor with Diagnostic and Calibration software	Semi-annually*			X
	Calibrate. (Check calibration, Recalibrate if necessary, Reset clock.)	Every 12 months or 2,000 hr			X
Suction	Take Calibration measurements.	Biannually (every 2 years)		X	
	Perform a Calibration check. Calibrate as necessary.	Every 300 hr. of operation		X	
	-Maximum Low Vacuum Level Limit.			X	
	-Intermittent on/off timing circuits			X	
Oxygen	N/A - See Preventive Maintenance Tasks				
Defibrillator	N/A - See Preventive Maintenance Tasks				
DDLS	Recalibrate Temperature sensors	Annually		X	
	Recalibrate Tilt sensor	Annually		X	
	Recalibrate Humidity sensor	Annually		X	
	Calibrate the Accelerometer	Annually		X	

			MAINTENANCE LEVEL (ORGANIZATIONAL [O], INTERMEDIATE [I], DEPOT [D])		
Subsystem	**CALIBRATION REQUIREMENT**	**FREQUENCY**	**O**	**I**	**D**
	Calibrate the Pressure sensor and compare with Physiological Monitor Pressure sensor	Annually		X	
Electrical Power System (EPS)	N/A - See Preventive Maintenance Tasks				
Environmental Control System (ECS)	N/A - See Preventive Maintenance Tasks				

* Vendor suggests quarterly due to type of usage

APPENDIX G User Comment Form

Integrated Medical Systems LSTAT User's Guide
Part No.

Integrated Medical Systems welcomes your comments and suggestions on the quality and usefulness of this publication. Your input is an important part of the information used for revision.

- Did you find any errors?
- Is the information clearly presented?
- Do you need more information? If so, where?
- Are the examples correct? Do you need more examples?
- What features did you like most about this manual?

If you find any errors or have any other suggestions for improvement, please indicate the topic, chapter, and page number below:

Please send your comments to:

Integrated Medical Systems
1984 Obispo Avenue
Signal Hill, CA 90274

Or e-mail a copy of this form to support@lstat.com

If you would like a reply, please give your name, address, and telephone number below:

Thank you for helping us to improve our documentation.

APPENDIX H Stylistic 1000

The Stylistic 1000 is a pen-based tablet computer equipped with a 100 megahertz (Mhz) 486 processor. The Stylistic 1000 comes with a monochrome transflective liquid crystal display (LCD). The display screen uses ambient light to illuminate the LCD and is best suited for outdoor use. The transflective display also has a backlight that can be turned on to illuminate the LCD when the ambient light level is too low. Figure H-1 shows the Stylistic 1000 features and controls.

Stylistic 1000 Pen Tablet Features

Features and controls that you use to operate the Stylistic 1000 pen tablet are described briefly below and illustrated in Figure H-1.

- **Main Power Switch:** This switch turns the main system unit power on and off.
- **Suspend/Resume button:** Allows you to suspend and resume pen tablet operation in order to optimize battery life. This button can also be configured as an On/Off switch.
- **Reset Button:** Pressing this button resets the system. (You can use the tip of the stylus to press the reset button.)
- **Status display:** Indicates the operational status of the pen tablet and the charge level of the battery.
- **Hotpads:** Hot-pads are stylus-sensitive icons below the bottom edge of the display screen that control the system's display and speaker settings. To use the hot-pads, tap on them with the stylus.
- **Stylus Holder:** The stylus holder provides a place to store he stylus when it is not in use.
- **ATA and PCMCIA Slot Access Door:** This door allows you to access both the ATA slot and the PCMCIA slots in your system unit.
- **PCMCIA Card Connector Access Door:** This door allows you to access connectors on PCMCIA cards installed in your system unit such as modems and LAN cards.
- **I/O Panel Access Door:** This door allows you to access the video port, R-232 serial port, and the parallel port on the system unit.
- **System Interface Port Access Door:** This door allows you to access the system interface port which is used with the port replicator.
- **Battery Charge Contacts:** The battery charge contacts on your system unit allow you to charge the battery in the system unit by placing the system unit on a custom battery charging device.
- **IrDA port:** The IrDA port on the system unit is an Infared Data Association (IrDA) compliant interface. You can use this port to receive and transmit data to other IrDA compliant devices.

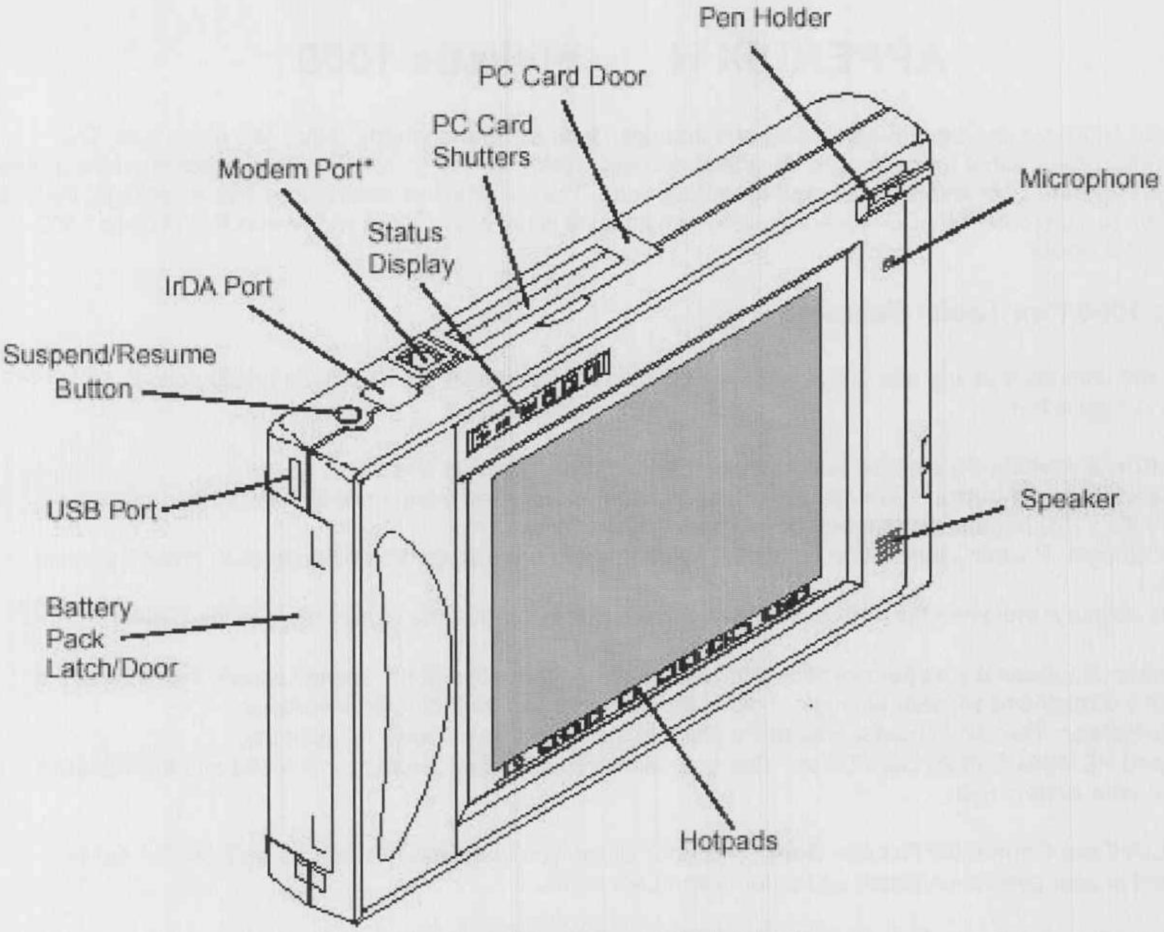

Pen Holder
PC Card Door
PC Card Shutters
Modem Port*
Microphone
Status Display
IrDA Port
Suspend/Resume Button
USB Port
Speaker
Battery Pack Latch/Door
Hotpads

Figure H-1 Stylistic 1000 PenTablet Features

Status Display

Icons that appear in the Status display are shown in Figure H-2.

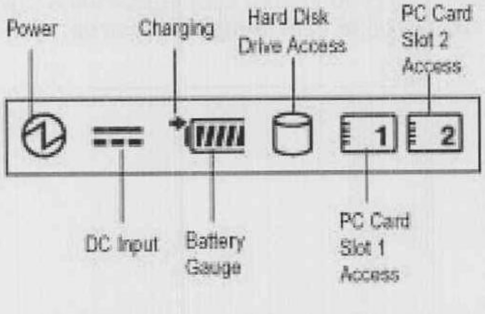

Power
Charging
Hard Disk Drive Access
PC Card Slot 2 Access
1
2
DC Input
Battery Gauge
PC Card Slot 1 Access

Figure H-2 Status Display

Operational modes for each of the status display icons are described below:

- **Power:** This icon is displayed when the computer is on. When the system is in suspend mode, this icon blinks.
- **DC Input:** This icon is displayed when an external power supply is connected to the DC input connector.
- **Charging:** The charging icon is a small arrow that appears above the battery gauge icon and is displayed when the battery pack is charging.
- **Battery Gauge:** This icon indicates the charge stored in the battery pack. The number of segments, or "cells" displayed in this icon indicates the percent of charge stored in the battery pack.
- **Hard Disk Drive Access:** This icon is displayed when the hard disk drive, flash memory card, or other storage device in the ATA slot is accessed.
- **PCMCIA Access:** These icons are displayed when PCMCIA cards in the respective slots are accessed.

Using the Stylus

The stylus has two switches, one (the stylus tip) is activated by pressing or tapping the stylus tip against the display screen; the other (the stylus button) is activated by pressing it with your finger. Figure H-3 shows the location of the stylus button and the stylus tip.

Using the stylus to select items or position the cursor on your screen is similar to using a mouse with a desktop computer. Tapping or holding the stylus tip against the screen is equivalent to clicking or holding the left mouse button. Pressing and holding the stylus button then tapping or holding the stylus tip against the screen is equivalent to pressing the right mouse button. The cursor will move wherever you point the stylus on the screen as long as the stylus tip is within a proximity of 0.8 inches of the screen surface.

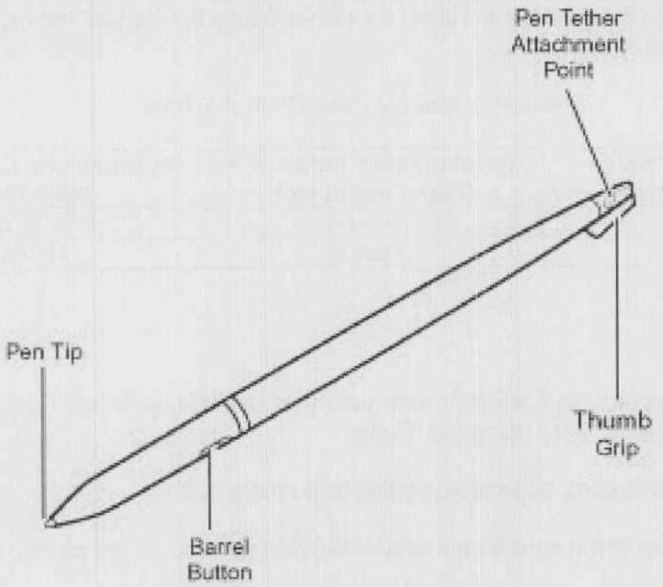


Figure H-3 Stylistic 1000 Pen

Using Hotpads

Hotpads are pen-active areas below the system display that you can use to change the display and speaker settings while the system is running. To use a hotpad, tap directly on it with the pen. You can also press and hold the pen tip against the Volume, Contrast, and Brightness hotpads to automatically repeat the hotpad function. The location of each hotpad is shown in Figure H-4.

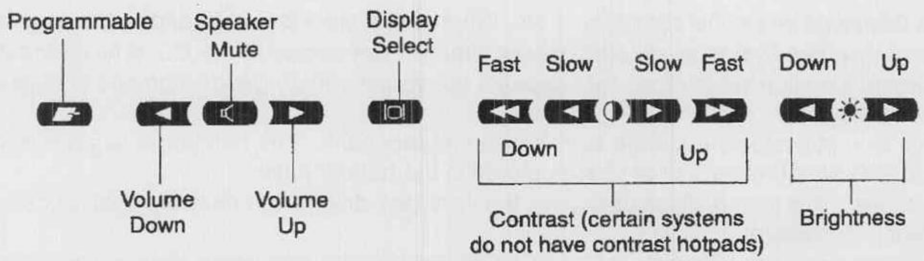


Figure H-4 Hotpads

Charging the Battery Pack

The Stylistic 1000 battery pack can be charged while it is installed in the pen tablet. To do so:

- Connect a DC power source, such as the LSTAT power and Ethernet adapter cable, to the DC input connector on the pen tablet. The DC input icon appears in the Status display. If the battery pack charge level is below 90%, the battery pack begins charging and the Charging icon appears in the Status display. If the battery pack charge is 90% or higher *when you connect* DC power, the battery pack will not charge; this prevents overcharging the battery pack.

As long as DC power *remains connected* to the pen tablet, the charging process continues until the battery pack charge reaches 100%. Charge times shown in Table H-1 are for a fully discharged battery pack charging both while the pen tablet is and is not in use.

Table H-1 Battery Pack Charging Time

Battery Pack Charge Level Reached	Approximate Charge Time (tablet not in use)	Approximate Charge Time (table in use)
90%	3 hours	9 to 10 hours
100%	5 hours	12 hours

PC Card Slots

The stylistic 1000 pen tablet has two PC Card slots that allow you to install up to two Type II PC Cards using both slots 1 and 2, or a single Type III PC Card using slot 1 only.

There are two ways to install a PC card, depending on the card configuration.

- If you need access to the top of the card after it is installed (as with some LAN cards), install the card through the PC card door shutters.
- If access to the card is not required after it is installed (as with flash memory), open the PC card door before installing the card.

If you need assistance installing a PC Card in the Stylistic 1000 pen tablet, contact Integrated Medical Systems support at support@lstat.com .

Avoid Overheating

The Stylistic 1000 pen tablet monitors its internal temperature. As the internal temperature approaches the tolerable limits of heat-sensitive components, system functions are automatically limited or turned off to prevent heat damage.

To avoid overheating the pen tablet:

- Do not obstruct the heat sink vents on the lower left edge of the pen tablet.
- Do not charge the pen tablet while it is in the harsh environment case unless the system is either suspended or off. Using proper power management techniques while the pen tablet is in the harsh environment case also helps to prevent overheating.

Replacing the Pen Tip

The pen tip is made of a soft plastic material. With use, the pen tip may become worn or may pick up abrasive particles that can scratch the display screen. A damaged or warped tip may not move freely, causing unpredictable results when using the pen. If your pen exhibits any of these problems, replace the pen tip. To do so:

1. Remove the pen tip by pulling it straight out of the pen.
3. Insert a new pen tip into the pen until it fits snugly.

You can now use the pen. Spare pen tips are included with the Stylistic 1000 pen tablet. Contact Integrated Medical Systems support at support@lstat.com to obtain a new pen tip if one is not available.

Note: The pen tip is held in the pen by friction. Removing and reinserting the pen tip repeatedly wears out the pen tip and it may pull out of the pen. It is a good idea to always have a spare pen tip available in case of damage; if the tip is damaged, do not use it.

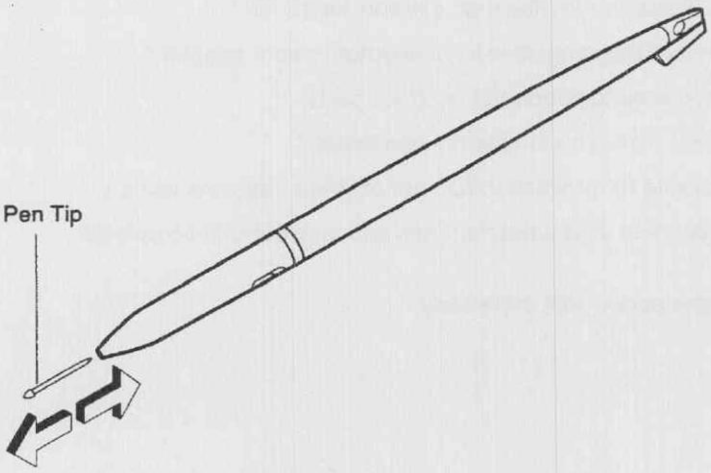


Figure H-5

APPENDIX I Stylistic 1200

Features and controls that you use to operate the Stylistic 1200 pen tablet are described briefly below.

- Status display: Indicates the operational status of the pen tablet.
- Pen: The main pointing device that you use to run programs and enter data. A pen holder is built into the pen tablet to store the pen when not in use.
- Power switch: Allows you to turn system power on or off.
- Suspend/Resume button: Allows you to suspend and resume system operation.
- Reset button: Restarts the system.
- Speaker: Allows you to play back audio files without external hardware.
- Microphone: Allows you to record sound such as voice messages.
- PC Card door: Allows you to access PC Cards installed in PC Card slots.
- IrDA port: Infrared interface for communication with devices compliant with IrDA Standard 1.1 or 1.0.
- Hotpads: Allow you to change display and speaker settings by tapping with the pen.
- Battery pack: Can be removed and charged in an optional external charger.*
- System interface port: Allows you to connect the Stylistic 1200 port replicator.*
- PS/2-style keyboard port: Allows you to attach an external keyboard.*
- DC power connector: Allows you to connect the AC adapter or auto adapter.*
- I/O connector door: Allows access to peripheral interface ports.
- Pen tether attachment points: Allow you to attach a pen tether.*
- Heat sink vents: Provide cooling for processor. (Do not obstruct heat sink vents.)
- Audio Jacks: Allow you to connect stereo headphones and an external microphone.

* These peripherals and accessories are sold separately.

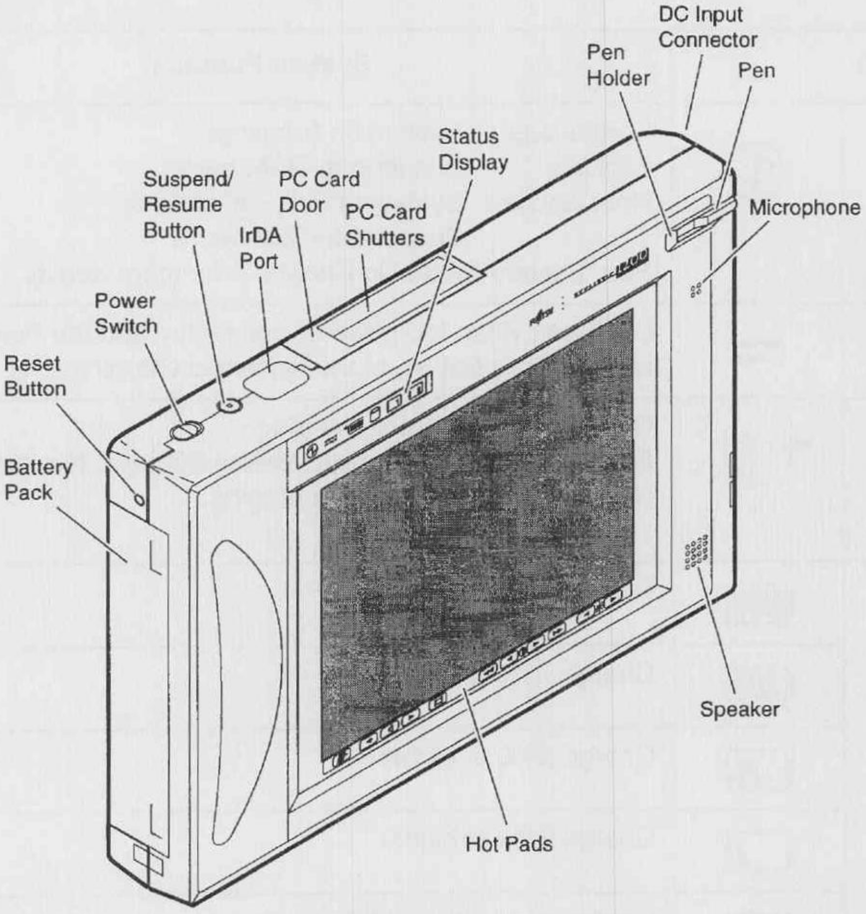

DC Input Connector
Pen Holder
Pen
Status Display
Suspend/ Resume Button
PC Card Door
PC Card Shutters
Microphone
IrDA Port
Power Switch
Reset Button
Battery Pack
Speaker
Hot Pads

Figure I-1

Status Display

Icons appear in the Status display indicating the status of system functions such as system power and battery charge level. The location of icons in the Status display is shown in Figure I-2.

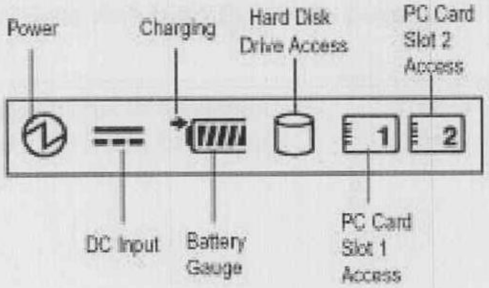

Power
Charging
Hard Disk Drive Access
PC Card Slot 2 Access
1
2
DC Input
Battery Gauge
PC Card Slot 1 Access

Figure I-2 Status Display Icons

The following table describes the appearance of individual icons in the Status display and the status indicated when the icon is displayed. (if an icon is not displayed, it indicates that the related system function is off or inactive.)

Table I-1 System Features

Icon		System Function
Power icon. Indicates system state.	⏻	Continuous: System on (running). Blinking: Suspend-to-RAM mode. Not displayed: System in Fully Off state or Suspend-to-Disk mode. See "System States" in Chapter 2 for more details.
DC Input icon.	⎓	Displayed when DC power is connected and the Power switch is in the On position, or the system is charging.
Charging icon (arrow displayed near Battery Gauge icon).	→ III	Continuous: Battery charging. Blinking: Battery temperature too high, charging stopped. Not displayed: Battery not charging.
Battery Gauge icon. This icon displays a number of "cells" to indicate the status of the battery pack. (Displayed when Power switch is on or battery pack is charging.)	IIIII	Charge 90% or higher
	IIII	Charge 75% or higher
	III	Charge 50% or higher
	II	Charge 25% or higher
	I	Continuous: 12% - 25% charge. Blinking cell: Less than 12% charge (low battery warning).
	⊏	Critically low battery charge. (System operation is suspended automatically.)
	I I	Cell short fault. Battery pack is bad.
Hard Disk Drive Access icon.	⛁	Displayed when IDE hard disk drive is active.
PC Card Access icons.	1 2	Icon 1: Displayed when PC Card slot 1 is active. Icon 2: Displayed when PC Card slot 2 is active.

Using Hotpads

Hotpads are pen-active areas below the system display that you can use to change the system's display and speaker settings while the system is running. To use the hotpads, tap directly on the desired hotpad; you can also tap and hold the pen tip against the Volume, Contrast, and Brightness hotpads to automatically repeat the hotpad function. The location of each hotpad is shown in Figure I-3.

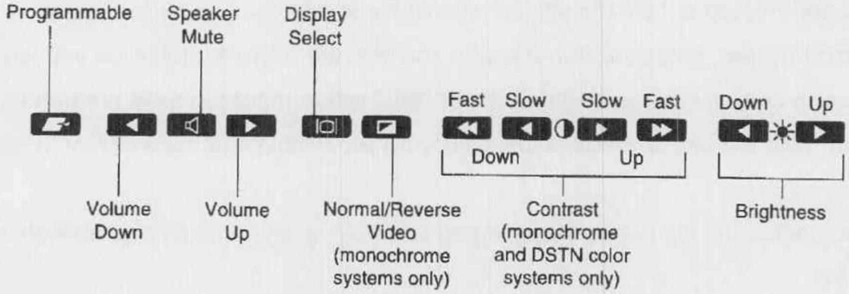


Figure I-3 Hotpads

A summary of each hotpad's function is given below:

- Programmable hotpad
  This hotpad can be programmed for application-specific functions. Contact your local help desk or reseller if you need assistance using the Programmable hotpad.

- Volume hotpads:
  These hotpads set the volume of the pen tablet speaker, or headphones if used. (Note that the speaker is disabled when headphones are plugged in.)

- Speaker Mute hotpad
  This hotpad turns the pen tablet speaker, or headphones if used, on or off. The system beeps when you tap this hotpad to turn on the speaker or headphones.

- Display Select hotpad
  This hotpad allows you to choose the pen tablet display screen, an external video monitor, or both as the selected system display. The pen tablet display screen appears blank when an external monitor exclusively is selected. Note that this hotpad is active regardless of whether an external monitor is connected to the pen tablet.

- Normal/Reverse Video hotpad (monochrome systems only)
  This hotpad allows you to choose normal or reverse video mode.

- Contrast hotpads (monochrome and DSTN color systems only)
  These hotpads allow you to adjust the display contrast.

- Brightness hotpads
  These hotpads allow you to adjust the display brightness.

Using the Pen

You can use the pen to select items and run programs on the Stylistic 1200 pen tablet much like you would a mouse on a desktop computer. Programs that support handwriting recognition also allow you to write characters directly on the screen with the pen.

The screen reacts with the pen when the pen tip is within about 3/8 inch (10 millimeters) of the screen. The pen has two switches, the Tip switch and the Barrel button switch. When activated, these switches generally correspond to the buttons on a two-button mouse; the Tip switch corresponds to the left mouse button and the Barrel button, when used in combination with the Tip switch, corresponds to the right mouse button.

Note: *You may need to tap the pen tip against the screen initially to turn on the pen. The pen turns off automatically to conserve the pen battery if not used for a period of approximately 3 to 5 minutes.*

Here are some hints that may help you use the pen more effectively.

- **To activate the Tip switch,** tap or hold the pen tip against the screen.
- **To activate the Barrel button,** press the Barrel button and hold the Barrel button in as you tap the pen tip on the screen. (This action corresponds to a right-click operation with a mouse in most programs.)
- **To move the cursor,** hold the pen tip close to the display screen (within about 3/8 inch or 10 millimeters) and move the pen.
- **To start a program,** double-tap the pen tip (tap the pen tip twice rapidly) on the program icon as you would double-click a mouse.
- **To select an object,** tap the pen tip once on the object.
- **To drag an object,** place the pen tip directly over the object, then press and hold the pen tip against the display screen while you move the pen.

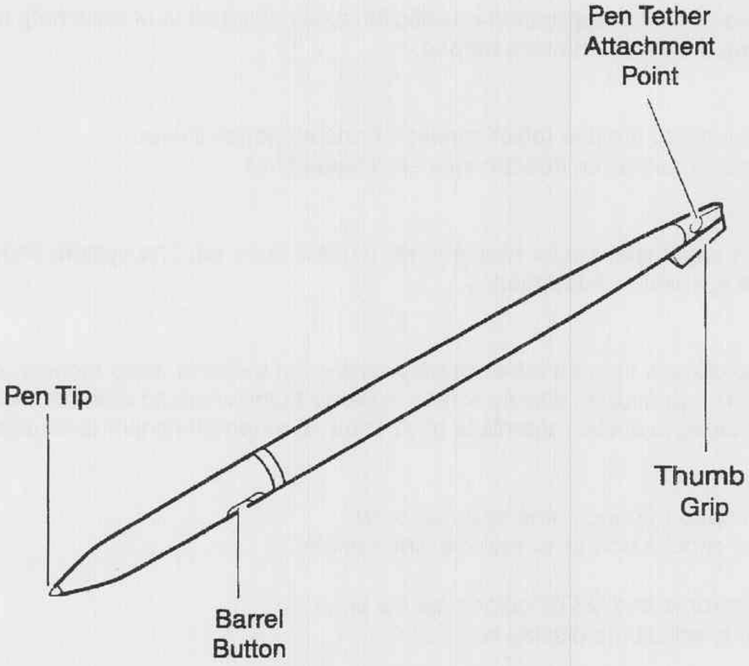


Figure I-4 Stylistic 1200 Pen

Charging the Battery Pack

The Stylistic 1200 battery pack can be charged while it is installed in the pen tablet. To do so:

- Connect a DC power source, such as the LSTAT power and Ethernet adapter cable, to the DC input connector on the pen tablet. The DC input icon appears in the Status display. If the battery pack charge level is below 90%, the battery pack begins charging and the Charging icon appears in the Status display. If the battery pack charge is 90% or higher *when you connect* DC power, the battery pack will not charge; this prevents overcharging the battery pack.

As long as DC power *remains connected* to the pen tablet, the charging process continues until the battery pack charge reaches 100%. The amount of time needed to charge the battery pack is shown in the table below. Charge times shown here are for a fully discharged 9-cell battery pack charging while the pen tablet is not in use.

Table I-2 Battery Pack Charging Time

Battery Pack Charge Level Reached	Approximate Charge Time
90%	3 hours
99%	4 hours
100%	5 hours

The pen tablet uses two charge modes to charge the battery pack, *Fast Charge* mode and *Slow Charge* mode. When the charge level is below 90%, the system charges the battery pack in Fast Charge mode; at 90% or higher, Slow Charge mode is used. This prevents the battery pack from being overcharged.

Avoid Overheating

The Stylistic 1200 pen tablet monitors the internal temperature of the pen tablet. As the internal temperature approaches the tolerable limit of heat-sensitive components, system functions are automatically limited or turned off to prevent heat damage. To avoid overheating, do not obstruct the heat sink vents on the lower edge of the pen tablet. If the system gets too hot, system operation is suspended automatically and the system will not allow you to resume operation until it is sufficiently cool.

Replacing the Pen Tip

The pen tip is made of a soft plastic material. With use, the pen tip may become worn or may pick up particles of dust or dirt that can scratch the display screen. Also, a damaged or warped tip may not move freely, causing unpredictable results when using the pen. If your pen exhibits any of these problems, replace the pen tip. To do so:

1. Remove the pen tip by pulling it straight out of the pen.
2. Insert a new pen tip into the pen until it fits snugly.

You can now use the pen. Spare pen tips are included with the Stylistic 1200 pen tablet. Contact Integrated Medical Systems support at support@lstat.com to obtain a new pen tip if one is not available.

Note: The pen tip is held in the pen by friction. Removing and reinserting the pen tip repeatedly wears out the pen tip and it may pull out of the pen.

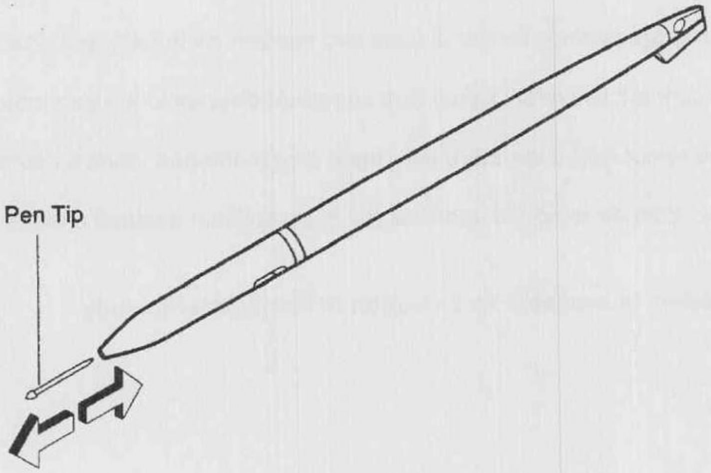


Figure I-5

APPENDIX J Stylistic 2300

The Stylistic 2300™ pen tablet is a high-performance, pen-based computer that is designed to support Windows 95, Windows 98, or Windows NT. The Stylistic 2300 pen-based computer has a 233 MHz Pentium® MMX™ processor. It is equipped with a Color Transflective (CTF) SVGA Liquid Crystal Display (LCD) and is best suited for outdoor use. Figure J-1 shows the Stylistic 2300 features and controls.

Stylistic 2300 Pen Tablet Features

Features and controls that you use to operate the Stylistic 2300 pen tablet are described briefly below and illustrated in Figure J-1.

Front Features:

- **Status display:** Indicates the operational status of the pen tablet and the charge level of the battery.
- **Pen:** The main pointing device that you use to run programs and enter data. A pen holder is built into the pen tablet to store the pen when not in use.
- **Suspend/Resume button:** Allows you to suspend and resume pen table operation in order to optimize battery life. This button can also be configured as an On/Off switch.
- **Speaker:** Allows you to play back audio files without external hardware.
- **Microphone:** Allows you to record sound such as voice messages.
- **PC Card door:** Allows you to access PC Cards installed in PC Card slots.
- **IrDA port:** Provides an infrared interface for communication with devices compliant with IrDA Standard Revision 1.1.
- **Hotpads:** Allows you to change settings for the display and speaker by tapping with the pen.
- **USB port:** Allows you to connect Universal Serial Bus-compliant devices to the pen tablet.
- **Modem port*:** Allows you to connect a standard telephone plug to the pen tablet's internal 56 Kbp modem.
- **Removable battery pack:** Can be removed and charged in an optional external charger.

*** The internal modem is available as an option in North America only.**

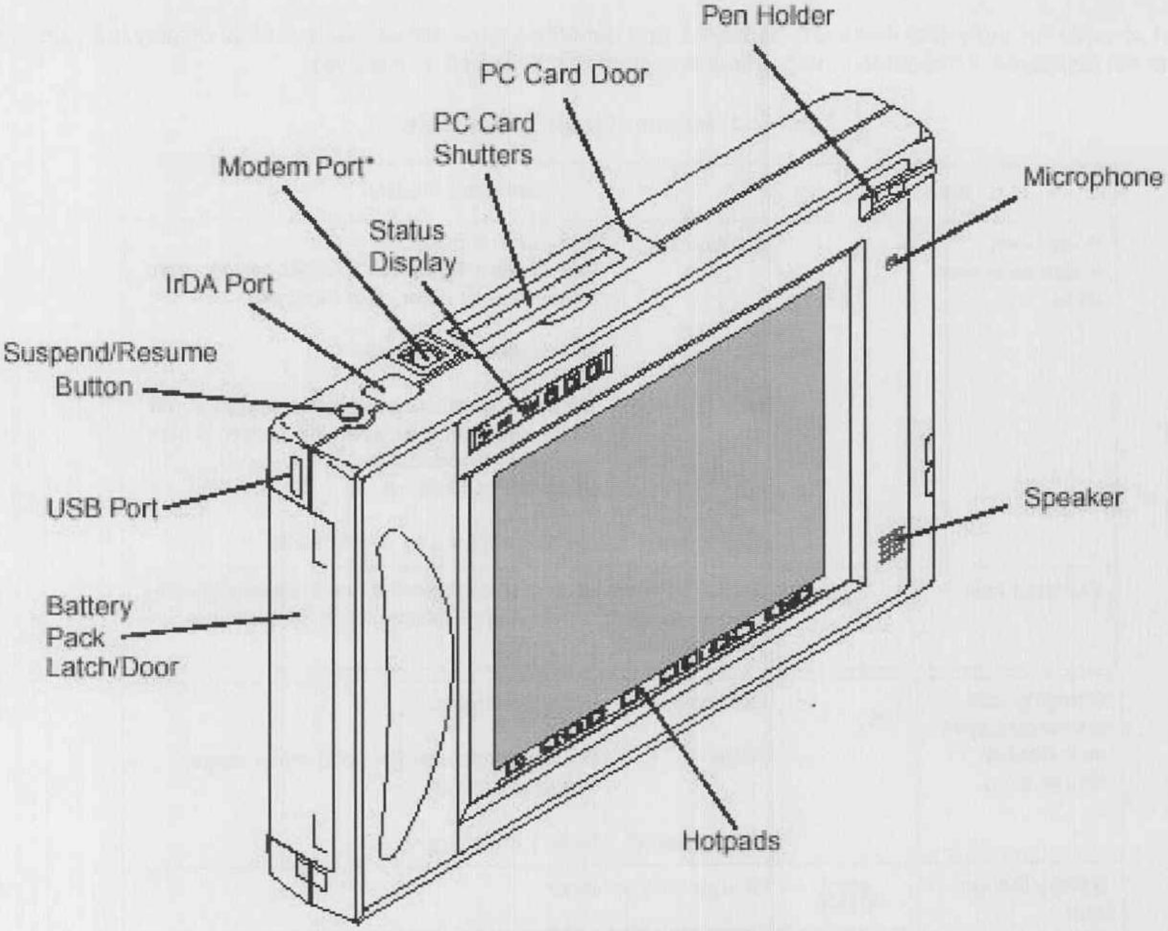

Pen Holder
PC Card Door
PC Card Shutters
Modem Port*
Status Display
IrDA Port
Suspend/Resume Button
USB Port
Battery Pack Latch/Door
Microphone
Speaker
Hotpads

Figure J-1 Stylistic 2300 PenTablet Features

Status Display

Icons appear in the Status display indicating the status of system functions such as system power and battery charge level. The location of icons in the Status display is shown in Figure J-2.

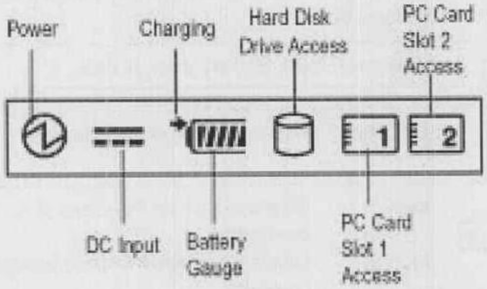

Power
Charging
Hard Disk Drive Access
PC Card Slot 2 Access
1
2
DC Input
Battery Gauge
PC Card Slot 1 Access

Figure J-2 Status Display Icons

Table J-1 shows how individual icons are displayed, and describes what the variations of that display indicate. (if an icon is not displayed, it indicates that the related system function is off or inactive).

Table J-1 System Status Indications

Icon		**System Function**
Power icon. Indicates system state.	⏻	Continuous: **Fully on** (running) **Idle or Standby state** (resumes activity when pen activity or other input detected). Blinking: **Suspend-to-RAM** mode. Not displayed: **Off** state (when suspend button is configured as a power button or when the system is shut down with a software exit.) **Suspend-to-Disk** mode See "System States" in Chapter 2 for more details.
DC Input icon.	⎓	Displayed when DC power is connected and the system is fully on or in suspend mode. Also displayed when the battery is being charged.
Charging icon (arrow displayed near Battery Gauge icon).	➔	Continuous: Battery charging. Blinking: Battery temperature out of thermal range, charging stopped. Not displayed: Battery not charging.
Battery Gauge icon. This icon displays a number of "cells" to indicate the status of the battery pack. (Displayed when power is on or battery pack is charging.)	IIIII	Charge 90% or higher
	IIII	Charge 75% - 90%
	III	Charge 50% - 75%
	II	Charge 25% - 50%
	I	Continuous: 12% - 25% charge. Blinking cell: Less than 12% charge (low battery warning).
	▭	Critically low battery charge. (System operation is suspended automatically.)
	I I	Cell short fault. Battery pack is bad.
Hard Disk Drive Access icon.	⛁	Displayed when hard disk drive is active.
PC Card Access icons.	1 2	Icon 1: Displayed when PC Card slot 1 is accessed by the computer. Icon 2: Displayed when PC Card slot 2 is accessed by the computer.

Using Hotpads

Hotpads are pen-active areas below the system display that you can use to change the display and speaker settings while the system is running. To use a hotpad, tap directly on it with the pen. You can also press and hold the pen tip against the Volume, Contrast, and Brightness hotpads to automatically repeat the hotpad function. The location of each hotpad is shown in Figure J-3.

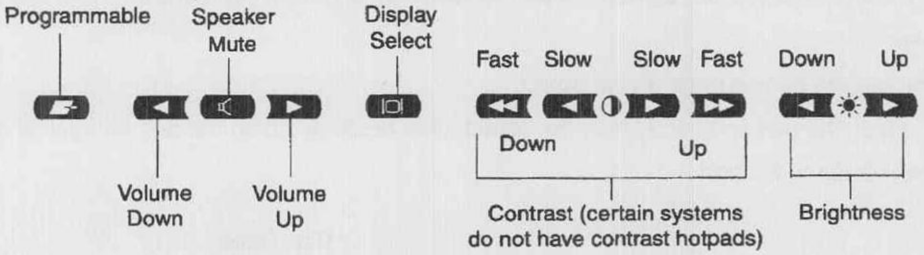


Figure J-3 Hotpads

Using the Pen

Caution

The Stylistic 2300 pen is a sophisticated, high-quality electronic instrument that can be damaged if used improperly. Treat the pen as you would any precision device. The following list contains guidelines for proper pen handling:

- Avoid gesturing with the pen, using it as a pointer, or tapping it on surfaces other than the pen tablet screen.
- Unscrew the pen only when you are changing the battery.
- Do not try to turn the thumb grip on the pen; it is designed for inserting and removing the pen from the pen holder and for attaching the pen tether.
- To avoid damage, the pen should be stored in the pen holder when not in use.

You can use the pen to select items and run programs on the Stylistic 2300 pen tablet like a mouse on a desktop computer. Programs that support handwriting recognition also allow you to write characters directly on the screen with the pen.

The screen reacts with the pen when the pen tip is approximately 3/8 inch (one centimeter) from the screen. The pen has two switches, the tip switch and the barrel button switch. When activated, these switches generally correspond to the buttons on a two-button mouse; the tip switch corresponds to the left mouse button and the barrel button switch, when used in combination with the tip switch, corresponds to the right mouse button.

Note: You may need to tap the pen tip against the screen initially to turn on the pen. The pen turns off Automatically to conserve the pen battery if not used for a period of approximately 3 minutes.

Here are some hints that may help you use the pen more effectively.

- **To activate the Tip switch,** tap or hold the pen tip against the screen.

- **To activate the Barrel button switch,** press and hold in the Barrel button switch, then tap the pen tip on the screen. (This action corresponds to a right-click operation with a mouse in most programs.)
- **To move the cursor,** hold the pen tip close to the display screen (within about 3/8 inch or 1 centimeter) and move the pen.
- **To start a program,** double-tap the pen tip (tap the pen tip twice rapidly) on the program icon as you would double-click a mouse.
- **To select an object,** tap the pen tip once on the object.
- **To drag an object,** place the pen tip directly over the object, then press and hold the pen tip against the display screen while you move the pen.

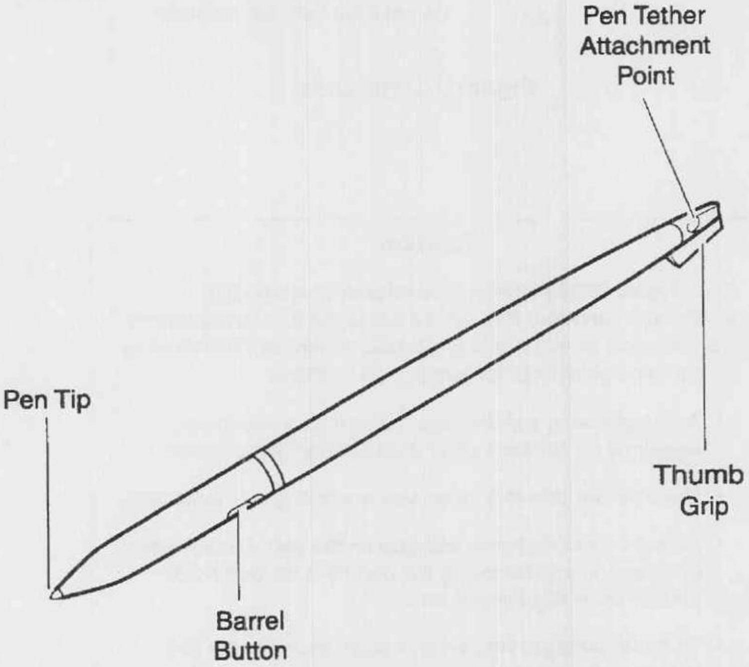


Figure J-4 Stylistic 2300 Pen

Charging the Battery Pack

The Stylistic 2300 battery pack can be charged while it is installed in the pen tablet. To do so:

- Connect a DC power source, such as the LSTAT power and Ethernet adapter cable, to the DC input connector on the pen tablet. The DC input icon appears in the Status display. If the battery pack charge level is below 90%, the battery pack begins charging and the Charging icon appears in the Status display. If the battery pack charge is 90% or higher *when you connect* DC power, the battery pack will not charge; this prevents overcharging the battery pack.

As long as DC power *remains connected* to the pen tablet, the charging process continues until the battery pack charge reaches 100%. Charge times shown in Table J-2 are for a fully discharged battery pack charging both while the pen tablet is and is not in use.

Table J-2 Battery Pack Charging Time

Battery Pack Charge Level Reached	Approximate Charge Time (tablet not in use)	Approximate Charge Time (table in use)
90%	3 hours	9 to 10 hours
100%	5 hours	12 hours

PC Card Slots

The stylistic 2300 pen tablet has two PC Card slots that allow you to install up to two Type II PC Cards using both slots 1 and 2, or a single Type III PC Card using slot 1 only.

There are two ways to install a PC card, depending on the card configuration.

- If you need access to the top of the card after it is installed (as with some LAN cards), install the card through the PC card door shutters.
- If access to the card is not required after it is installed (as with flash memory), open the PC card door before installing the card.

The stylistic 2300 pen tablet has two PC Card slots that allow you to install up to two Type II PC Cards using both slots 1 and 2, or a single Type III PC Card using slot 1 only.

If you need assistance installing a PC Card in the Stylistic 2300 pen tablet, contact Integrated Medical Systems support at support@lstat.com .

Avoid Overheating

The Stylistic 2300 pen tablet monitors its internal temperature. As the internal temperature approaches the tolerable limits of heat-sensitive components, system functions are automatically limited or turned off to prevent heat damage.

To avoid overheating the pen tablet:

- Do not obstruct the hat sink vents on the lower left edge of the pen tablet.
- Do not charge the pen tablet while it is in the harsh environment case unless the system is either suspended or off. Using proper power management techniques while the pen tablet is in the harsh environment case also helps to prevent overheating.

Replacing the Pen Tip

The pen tip is made of a soft plastic material. With use, the pen tip may become worn or may pick up abrasive particles that can scratch the display screen. A damaged or warped pen tip may not move freely, causing unpredictable results when using the pen. If your pen exhibits any of these problems, replace the pen tip. To do so:

1. Remove the pen tip by pulling it straight out of the pen.
4. Insert a new pen tip into the pen until it fits snugly.

You can now use the pen. Spare pen tips are included with the Stylistic 2300 pen tablet. Contact Integrated Medical Systems support at support@lstat.com to obtain a new pen tip if one is not available.

Note: The pen tip is held in the pen by friction. Removing and reinserting the pen tip repeatedly wears out the pen tip and it may pull out of the pen. It is a good idea to always have a spare pen tip available in case of damage; if the tip is damaged, do not use it.

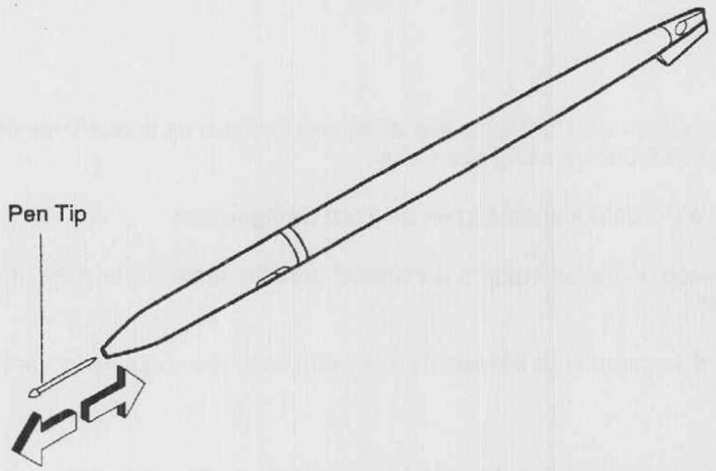


Figure J-5

APPENDIX K Secondary Display Error Messages

	Error Message Text	What it means/Possible Problem(s)
MAIN	Waiting for Physiological Monitor numeric data.	Secondary Display is not receiving Physiological Monitor numeric data:
		1. LSTAT is not responding (possibly off).
		2. Physiological Monitor is not responding (possibly off).
		3. Ethernet communication has been interrupted.
	Waiting for Physiological Monitor Alarm data.	Secondary Display is not receiving Physiological Monitor Alarm data:
		1. LSTAT is not responding (possibly off).
		2. Physiological Monitor is not responding (possibly off).
		3. Ethernet communication has been interrupted.
	Waiting for Physiological Monitor ECG	Secondary Display is not receiving Physiological Monitor ECG
	waveform data.	waveform data:
		1. LSTAT is not responding (possibly off).
		2. Physiological Monitor is not responding (possibly off).
		3. Ethernet communication has been interrupted.
	Waiting for Ventilator numeric data.	Secondary Display is not receiving Ventilator numeric data:
		1. LSTAT is not responding (possibly off).
		2. Ventilator is not responding (possibly off).
		3. Ethernet communication has been interrupted.
	Physiological Monitor -- invalid ECG waveform	Secondary Display is receiving invalid ECG waveform data:
	data.	1. ECG sensor is not connected correctly to the Physiological Monitor.
		2. Physiological Monitor is not yet in INSERV mode.
	Physiological Monitor -- invalid numeric data.	Not Used.
	Ventilator -- invalid numeric data.	Not Used.
	Physiological Monitor -- numeric data packet error.	Secondary Display has detected an error when reading the numeric
		data from the Physiological Monitor.
	Physiological Monitor -- unrecognized item in	Secondary Display has detected an invalid data item number when
	numeric data packet.	reading the numeric data from the Physiological Monitor.
	Ventilator -- numeric data packet error.	Secondary Display has detected an error when reading the numeric
		data from the Ventilator.
PHYSIO	Waiting for Physiological Monitor numeric data.	Secondary Display is not receiving Physiological Monitor numeric data:
		1. LSTAT is not responding (possibly off).
		2. Physiological Monitor is not responding (possibly off).
		3. Ethernet communication has been interrupted.
	Waiting for Physiological Monitor Alarm data.	Secondary Display is not receiving Physiological Monitor Alarm data:
		1. LSTAT is not responding (possibly off).
		2. Physiological Monitor is not responding (possibly off).
		3. Ethernet communication has been interrupted.

	Error Message Text	**What it means/Possible Problem(s)**
	Waiting for Physiological Monitor ECG waveform data.	Secondary Display is not receiving Physiological Monitor ECG waveform data: 1. LSTAT is not responding (possibly off). 2. Physiological Monitor is not responding (possibly off). 3. Ethernet communication has been interrupted.
	Waiting for Physiological Monitor P1 waveform data.	Secondary Display is not receiving Physiological Monitor P1 waveform data: 1. LSTAT is not responding (possibly off). 2. Physiological Monitor is not responding (possibly off). 3. Ethernet communication has been interrupted.
	Waiting for Physiological Monitor P2 waveform data.	Secondary Display is not receiving Physiological Monitor P2 waveform data: 1. LSTAT is not responding (possibly off). 2. Physiological Monitor is not responding (possibly off). 3. Ethernet communication has been interrupted.
	Physiological Monitor -- invalid ECG waveform data.	Secondary Display is receiving invalid ECG waveform data: 1. ECG sensor is not connected correctly to the Physiological Monitor. 2. Physiological Monitor is not yet in INSERV mode.
	Physiological Monitor -- invalid P1 waveform data.	Secondary Display is receiving invalid P1 waveform data: 1. P1 sensor is not connected correctly to the Physiological Monitor. 2. Physiological Monitor is not yet in INSERV mode.
	Physiological Monitor -- invalid P2 waveform data.,	Secondary Display is receiving invalid P2 waveform data: 1. P2 sensor is not connected correctly to the Physiological Monitor. 2. Physiological Monitor is not yet in INSERV mode.
	Physiological Monitor -- invalid numeric data.	Not Used.
	Physiological Monitor -- numeric data packet error.	Secondary Display has detected an error when reading the numeric data from the Physiological Monitor.
	Physiological Monitor -- unrecognized item in numeric data packet.	Secondary Display has detected an invalid data item number when reading the numeric data from the Physiological Monitor.
	Physiological Monitor -- breath rate value inconsistent.	Not Used.
	Re-syncing waveforms ... Re-syncing waveforms.	Secondary Display software had detected that the ECG, P1 & P2 waveforms are no longer synchronized. Automatic resyncing is taking place.
CO2	Waiting for CO2 numeric data.	Secondary Display is not receiving Physiological Monitor numeric data: 1. LSTAT is not responding (possibly off). 2. Physiological Monitor is not responding (possibly off). 3. Ethernet communication has been interrupted.
	Waiting for CO2 alarm data.	Secondary Display is not receiving Physiological Monitor Alarm data: 1. LSTAT is not responding (possibly off).

	Error Message Text	What it means/Possible Problem(s)
		2. Physiological Monitor is not responding (possibly off).
		3. Ethernet communication has been interrupted.
	Waiting for CO2 waveform data.	Secondary Display is not receiving Physiological Monitor CO2 waveform data:
		1. LSTAT is not responding (possibly off).
		2. Physiological Monitor is not responding (possibly off).
		3. Ethernet communication has been interrupted.
	CO2 -- invalid CO2 waveform data.	Secondary Display is receiving invalid CO2 waveform data:
		1. CO2 sensor is not connected correctly to the Physiological Monitor.
		2. Physiological Monitor is not yet in INSERV mode.
		3. CO2 sensor is warming-up.
	CO2 -- invalid numeric data.	Not Used.
	CO2 -- numeric data packet error.	Secondary Display has detected an error when reading the numeric data from the Physiological Monitor.
	CO2 -- unrecognized item in numeric data packet.	Secondary Display has detected an invalid data item number when reading the numeric data from the Physiological Monitor.
SpO2	Waiting for SpO2 numeric data.	Secondary Display is not receiving Physiological Monitor numeric data:
		1. LSTAT is not responding (possibly off).
		2. Physiological Monitor is not responding (possibly off).
		3. Ethernet communication has been interrupted.
	Waiting for SpO2 alarm data.	Secondary Display is not receiving Physiological Monitor Alarm data:
		1. LSTAT is not responding (possibly off).
		2. Physiological Monitor is not responding (possibly off).
		3. Ethernet communication has been interrupted.
	Waiting for SpO2 waveform data.	Secondary Display is not receiving Physiological Monitor SpO2 waveform data:
		1. LSTAT is not responding (possibly off).
		2. Physiological Monitor is not responding (possibly off).
		3. Ethernet communication has been interrupted.
	SpO2 -- invalid SpO2 waveform data.	Secondary Display is receiving invalid SpO2 waveform data:
		1. SpO2 sensor is not connected correctly to the Physiological Monitor.
		2. Physiological Monitor is not yet in INSERV mode.
	SpO2 -- invalid number data.	Not Used.
	SpO2 -- numeric data packet error.	Secondary Display has detected an error when reading the numeric data from the Physiological Monitor.
	SpO2 -- unrecognized item in numeric data packet.	Secondary Display has detected an invalid data item number when reading the numeric data from the Physiological Monitor.
VENT	Waiting for Ventilator numeric data.	Secondary Display is not receiving Ventilator numeric data:
		1. LSTAT is not responding (possibly off).
		2. Ventilator is not responding (possibly off).
		3. Ethernet communication has been interrupted.

	Error Message Text	What it means/Possible Problem(s)
	Waiting for Ventilator waveform data.	Secondary Display is not receiving Ventilator waveform data: 1. LSTAT is not responding (possibly off). 2. Ventilator is not responding (possibly off). 3. Ethernet communication has been interrupted.
	Impact Ventilator -- numeric data packet error.	Secondary Display has detected an error when reading the numeric data from the Ventilator.
	Impact Ventilator -- alarm data packet error.	Secondary Display has detected an error when reading the alarm data from the Ventilator.
	Ventilator -- bad waveform data rate error.	Depending on the version of the Ventilator software, the rate at which the waveform data is updated can be either 50 ms (old) or 100 ms (new). If the data rate is not either one of these rates, this error message will be displayed.
VITALS	Waiting for Vital Signs data.	Secondary Display is not receiving Vital Signs data: 1. LSTAT is not responding (possibly off). 2. Physiological Monitor is not responding (possibly off). 3. Ethernet communication has been interrupted.
	Vital Signs -- data packet error.	Secondary Display has detected an error when reading the Vitals Signs data.
	No Vital Signs data received.	"Waiting for Vital Signs data" message may change to this message if LSTAT is not responding or ethernet connection is broken and the Secondary Display does not receive data within 2 minutes.
	Vital Signs data out of date.	Secondary Display has not had an update to the Vital Signs data in 3 minutes.
IV	Waiting for IV data.	Secondary Display is not receiving IV data: 1. LSTAT is not responding (possibly off). 2. IV unit is not responding (possibly off). 3. Ethernet communication has been interrupted.
	IV -- data packet error.	Secondary Display has detected an error when reading the IV data.
ISTAT	Waiting for ISTAT data.	Secondary Display is not receiving ISTAT data: 1. LSTAT is not responding (possibly off). 2. Ethernet communication has been interrupted.
	No ISTAT data available (data length = 0).	There are no ISTAT records stored on the LSTAT.
	Bad ISTAT data record.	Incorrect ISTAT record size.
UTIL_OV	Waiting for Discrete numeric data.	Secondary Display is not receiving Discrete data: 1. LSTAT is not responding (possibly off). 2. Ethernet communication has been interrupted.

	Error Message Text	**What it means/Possible Problem(s)**
	Oxygen Supply OVER PRESSURE condition.	Internal oxygen supply level is above the acceptable maximum (3200 psi).
	Discrete data packet error.	Secondary Display has detected an error when reading the discrete data.
UTIL_TEMP	Waiting for Discrete numeric data.	Secondary Display is not receiving Discrete data: 1. LSTAT is not responding (possibly off). 2. Ethernet communication has been interrupted.
	Temperature OUT OF RANGE.	One of the LSTAT temperature readings is out of the acceptable range.
	Discrete data packet error.	Secondary Display has detected an error when reading the discrete data.
UTIL_PWR	Waiting for Discrete numeric data.	Secondary Display is not receiving Discrete data: 1. LSTAT is not responding (possibly off). 2. Ethernet communication has been interrupted.
	Power Battery Level OUT OF RANGE.	The Power digital discrete signal indicates that no Battery LEDs are lit.
	Discrete data packet error.	Secondary Display has detected an error when reading the discrete data.
UTIL_SLED	Waiting for Sled numeric data.	Secondary Display is not receiving Discrete data: 1. LSTAT is not responding (possibly off). 2. Ethernet communication has been interrupted.
	Sled discrete data packet error.	Secondary Display has detected an error when reading the sled data.
SYSTEM	Waiting for Discrete numeric data.	Secondary Display is not receiving Discrete data: 1. LSTAT is not responding (possibly off). 2. Ethernet communication has been interrupted.
	Waiting for Health & Safety data.	Secondary Display is not receiving Health & Safety data: 1. LSTAT is not responding (possibly off). 2. Ethernet communication has been interrupted.
	Discrete data packet error.	Secondary Display has detected an error when reading the discrete data.
	Health and Safety data packet error.	Secondary Display has detected an error when reading the health and safety data.
DEFIB	Waiting for Defibrillator ECG waveform data.	Secondary Display is not receiving Defibrillator data: 1. LSTAT is not responding (possibly off). 2. Defibrillator is not responding (possibly off). 3. Ethernet communication has been interrupted. 4. Defibrillator was turned on before LSTAT finished its initialization period.

	Error Message Text	**What it means/Possible Problem(s)**
	Stand clear, push flashing button to rescue.	This message may appear in Message Field 2 when the Defibrillator is ready to rescue and announcing the same message.
FLO TRAK	Waiting for FloTrak Flow waveform data.	Secondary Display is not receiving FloTrak Flow data: 1. LSTAT is not responding (possibly off). 2. Ethernet communication has been interrupted.
	Waiting for FloTrak Volume waveform data.	Secondary Display is not receiving FloTrak Volume data: 1. LSTAT is not responding (possibly off). 2. Ethernet communication has been interrupted.
	Waiting for FloTrak Numeric Data.	Secondary Display is not receiving FloTrak numeric data: 1. LSTAT is not responding (possibly off). 2. Ethernet communication has been interrupted.
	The following 9 errors are sent within the FloTrak message itself:	
	1. Sensor not connected.	FloTrak sensor is disconnected.
	2. Zero or purge in progress.	FloTrak zeroing or purging in progress.
	3. Sensor not valid.	Sensor is not one of the valid FloTrak sensor types.
	4. Hardware Error - Error zeroing flow channel.	Try re-zeroing to correct this problem. If the error persists, return to the factory for servicing.
	5. Hardware Error - Error zeroing airway channel.	Try re-zeroing to correct this problem. If the error persists, return to the factory for servicing.
	6. Hardware Error - Error zeroing 2nd airway channel.	(Optional Hardware required) Try re-zeroing to correct this problem. If the error persists, return to the factory for servicing.
	7. Hardware Error - Barometric pressure out of range.	Barometric pressure out of range (400 - 800 mmHg). Return to the factory for servicing.
	8. Warning - No respiration time-out.	Timed out due to no respiration reading. Usually occurs when Ventilator is not on.
	9. CO2 connected.	No CO2 connected. (Optional hardware required.)
	FloTrak numeric data packet error.	Secondary Display has detected an error when reading the FloTrak numeric data.
TREND	Waiting for Trend data.	Secondary Display is not receiving Trend data: 1. LSTAT is not responding (possibly off). 2. Physiological Monitor is not responding (possibly off). 3. Ethernet communication has been interrupted.
	Trend -- packet error.	Secondary Display has detected an error when reading the Trend data.
	No Trend data received.	"Waiting for Trend data" message may change to this message

	Error Message Text	What it means/Possible Problem(s)
		if LSTAT is not responding or ethernet connection is broken and the Secondary Display does not receive data within 2 minutes.
	Trend data out of date.	Secondary Display has not had an update to the Trend data in 3 minutes.
All	Error found in data packet.	Data is packaged incorrectly when sent to the Secondary Display.
	Master alarms are unavailable. Check communication link.	Secondary Display is not receiving the master alarm message (nor the ID message). Assumes a disconnect between LSTAT and Secondary Display. LSTAT could be turned off, in maintenance mode or disconnected from the network/Secondary Display.
	Master alarms are unavailable. Incompatible embedded software version.	Secondary Display is not receiving the master alarm message. Probable cause: LSTAT is running a pre-V1.3 embedded software version. (Master alarms were not implemented until V1.3 embedded software version.)

APPENDIX L OPERATOR'S SHIFT CHECKLIST

Name: ______________________ **Shift:** ______ **Location:** ____________________

Mfr/Model No.: _____________________ **Serial No. or Facility No.:** _____________________

	Check if Okay	Corrective Action/Remarks
LSTAT Unit Clean, no spills, clear of objects on top		
Inspect cases for damage (sled, infusion pump, blood analyzer, secondary display)		
Suction bottle connected and secured in enclosure		
Blood analyzer in foot fairing enclosure		
Cables/Hoses/Connectors Inspect for cracks, broken wire, or damage		
Connectors engage securely		
Power Supply Battery powered Verify fully charged battery		
AC/Battery backup power Plugged into live outlet		
Battery charging		
Internal Oxygen Verify bottle installed and latches secure		
Verify pressure at 3000 psi		
Self-Tests okay (ventilator, physiological monitor, defibrillator, infusion pump, blood analyzer)		
Indicators/Displays Power-on indicators working (system power, battery, O_2 ready, external O_2, fan, medical devices)		
Battery indicators LSTAT battery level indicators working		
Low battery indicators off (LSTAT, physiological monitor, infusion pump, blood analyzer)		
Charging indicators working (LSTAT, physiological monitor)		
Oxygen indicators Internal oxygen level indicators working		
Empty indicator off		
Over pressure indicator off		
DDLS indicators Status indicator: green		
Disk mode indicators off		
Over temperature indicator off		
LCDs working (ventilator, physiological monitor, DDLS two-line, secondary display, IV, blood analyzer)		
Secondary Display Utility Screens		
Power readouts within range		
Temperature readouts within range		
Alarm/Equipment failure indicators and message displays off		
Audible alarms working		
Filters Inspect filters for dirt, lint or serviceability (ventilator inlet, particulate, EMI)		
Supplies Inspect accessory bag per supply list provided in bag		

Signature: ________________________________ Date: _____________

OPERATOR'S SHIFT CHECKLIST FOR AUTOMATED DEFIBRILLATORS

Name: ______________________ **Shift:** ______ **Location:** ____________________

Mfr/Model No.: _____________________ **Serial No. or Facility No.:** _____________________

	Check if Okay	Corrective Action/Remarks
Defibrillator Unit Clean, no spills, clear of objects on top		
Defibrillator Pads Set of two pads, sealed, within expiration date		
Spare pads		
Cables/Connectors Inspect for cracks, broken wire, or damage		
Connectors engage securely		
Supplies Hand towel		
Scissors		
Razor		
Alcohol wipes		
Power Supply Battery powered Verify fully charged battery		
AC/Battery backup power Plugged into live outlet		
Battery Charging		
Test on battery power and reconnect to AC		
Indicators Power-on indicator working		
Self-test okay		
"Check unit" service indicator off		
Low battery indicator off		
Charge indicator working		
Audible alarms/prompts: disconnected cables, charging, "rescue" shock		
Charge/Display Cycle Disconnect AC plug		
Attach to simulator		
Detects, charges, and delivers shock for "VF"		
Responds correctly to non-shockable rhythms		

Check the appropriate box after each use of the checklist.

☐ No action required.
☐ Minor problem(s) corrected.
☐ Disposable supplies replaced.
☐ Major problem(s) identified. (OUT OF SERVICE.)

Signature: ______________________________ Date: ____________

APPENDIX M i-STAT Test Data Sheets

SODIUM/NA

Sodium is measured by ion-selective electrode potentiometry. In the calculation of results for sodium, concentration is related to potential through the Nernst equation. The performance characteristics of the sensors are equivalent in all cartridge configurations.

The i-STAT System uses direct (undiluted) electrochemical methods. Values obtained by direct methods may differ from those obtained by indirect (diluted) methods.[1]

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[2]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for sodium, as part of the i-STAT System, is intended for use in the *in vitro* quantification of arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for measurement of specific analytes and a buffered aqueous calibrant solution of known concentrations. For cartridges that contain a sensor for the measurement of sodium, the calibrant solution contains 140 mmol/L of sodium.

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range[3]
Sodium/Na	mmol/L (mEq/L)	100–180	138 – 146

i-STAT measurements are performed on whole blood specimens. The i-STAT System has been calibrated to agree with standard laboratory and reference methods typically performed on serum or plasma. Therefore, the reference ranges presented above are equivalent to reference ranges derived from serum or plasma measurements with standard laboratory methods.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

*The i-STAT System can be configured with the preferred units.

Clinical Significance

Tests for sodium in the blood are important in the diagnosis and treatment of patients suffering from hypertension, renal failure or impairment, cardiac distress, disorientation, dehydration, nausea and diarrhea. Some causes of increased values for sodium include dehydration, diabetes insipidus, salt poisoning, skin losses, hyperaldosteronism and CNS disorders. Some causes for decreased values for sodium include dilutional hyponatremia (cirrhosis), depletional hyponatremia and syndrome of inappropriate ADH.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using NCCLS guideline EP9-A[4]. Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on comparative methods within 20 minutes of collection.

Deming regression analysis[5] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Interference studies were based on NCCLS guideline EP7.[6]

*The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[4] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (mmol/L or mEq/L)

Aqueous Control	Mean	SD	%CV
Level 1	113.5	0.61	0.5
Level 3	141.7	0.71	0.5

Method Comparison (mmol/L or mEq/L)

	Beckman Synchron CX®3	Kodak Ektachem™ 700	Nova STAT Profile® 5
n	189	142	192
Sxx	0.74	0.52	0.54
Syy	0.53	0.58	0.53
Slope	1.00	0.98	0.95
Int't	-0.11	3.57	5.26
Sy.x	1.17	1.04	1.53
Xmin	1 26	1 20	1 24
Xmax	1 48	1 48	1 48
r	0.865	0.937	0.838

Cartridge Comparison

The performance characteristics of the sensors are equivalent in all cartridge configurations. System difference analysis was performed on 40 patient samples using the i-STAT 6+ and i-STAT EC4+ cartridges. In the 130–150 mmol/L range the average difference was 0.750.

Factors Affecting Results*

Sodium heparin may increase sodium results up to 1mmol/L.

*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

Interferent	Effect
β-hydroxybutyrate	16 mmol/L (166 mg/dL) β-hydroxybutyrate will decrease sodium results by 4 mmol/L.

References

1. N.W. Tietz, E.L. Pruden, O. Siggaard-Andersen, "Electrolytes " in Tietz Textbook of Clinical Chemistry—Second Edition, C.A. Burtis and E.R. Ashwood, eds. (Philadelphia: W.B. Saunders Company, 1994).

2. D.S. Young, Effects of Drugs on Clinical Laboratory Tests, 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

3. B.E. Statland, Clinical Decision Levels for Lab Tests (Oradell, NJ: Medical Economic Books, 1987).

4. NCCLS. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline.* NCCLS document EP9-A [ISBN 1-56238-283-7]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 1995.

5. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method-Comparison Analysis," Clinical Chemistry 25:3, 432 (1979).

6. NCCLS. *Interference Testing in Clinical Chemistry; Proposed Guideline.* NCCLS document EP7-P [ISBN 1-56238-020-6]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 1986.

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POTASSIUM/K

Potassium is measured by ion-selective electrode potentiometry. In the calculation of results for potassium, concentration is related to potential through the Nernst equation. The performance characteristics of the sensors are equivalent in all cartridge configurations.

The i-STAT System uses direct (undiluted) electrochemical methods. Values obtained by direct methods may differ from those obtained by indirect (diluted) methods.[1]

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[2]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for potassium, as part of the i-STAT System, is intended for use in the *in vitro* quantification of arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for measurement of specific analytes and a buffered aqueous calibrant solution of known concentrations. For cartridges that contain a sensor for the measurement of potassium, the calibrant solution contains 4 mmol/L of potassium.

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range[3]
Potassium/K	mmol/L(mEq/L)	2 – 9	3.5 – 4.9**

*The i-STAT System can be configured with the preferred units.

** The reference range for potassium listed above has been reduced by 0.2mmol/L from the range cited in Reference 3 to account for the difference between serum and plasma results.

i-STAT measurements are performed on whole blood specimens. The i-STAT System has been calibrated to agree with standard laboratory and reference methods typically performed on serum or plasma. Therefore, the reference ranges presented above are equivalent to reference ranges derived from serum or plasma measurements with standard laboratory methods.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

Tests for potassium in the blood are important in the diagnosis and treatment of patients suffering from hypertension, renal failure or impairment, cardiac distress, disorientation, dehydration, nausea and diarrhea. Some causes of increased values for potassium include renal glomerular disease, adrenocortical insufficiency, diabetic ketacidosis (DKA), sepsis and in vitro hemolysis. Some causes of decreased values for potassium include renal tubular disease, hyperaldosteronism, treatment of DKA, hyperinsulinism, metabolic alkalosis and diuretic therapy.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below. Method comparison data were collected using NCCLS guideline EP9-A[4]. Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on comparative methods within 20 minutes of collection.

Deming regression analysis[5] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Interference studies were based on NCCLS guideline EP7.[6]

* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[4] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (mmol/L or mEq/L)

Aqueous Control	Mean	SD	%CV
Level 1	5.61	0.064	1.14
Level 3	2.76	0.047	1.70

Method Comparison (mmol/L or mEq/L)

	Beckman Synchron CX®3	Kodak Ektachem™ 700	Nova STAT Profile® 5
n	189	142	192
Sxx	0.060	0.031	0.065
Syy	0.055	0.059	0.055
Slope	0.97	1.06	0.99
Int't	0.02	-0.15	-0.01
Sy.x	0.076	0.060	0.112
Xmin	2.8	3.0	2.8
Xmax	5.7	9.2	5.8
r	0.978	0.993	0.948

Cartridge Comparison

The performance characteristics of the sensors are equivalent in all cartridge configurations. System difference analysis was performed on 40 patient samples using the i-STAT 6+ and i-STAT EC4+ cartridges. In the 3.0–5.0 mmol/L range the average difference was 0.049.

Factors Affecting Results*

If heparinized whole blood is allowed to stand before testing, potassium values will first decrease slightly, then increase over time. Potassium values will increase in iced specimens.

Potassium values from anticoagulated samples are preferred to serum values because 0.1 to 0.7 mmol/L potassium can be released from platelets[1] and red blood cells during the clotting process. Potassium values obtained from skin puncture samples may vary due to hemolysis or an increase in tissue fluid from improper technique during the collection procedure.

*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

References

1. N.W. Tietz, E.L. Pruden, O. Siggaard-Andersen, "Electrolytes " in Tietz Textbook of Clinical Chemistry—Second Edition, C.A. Burtis and E.R. Ashwood, eds. (Philadelphia: W.B. Saunders Company, 1994).

2. D.S. Young, Effects of Drugs on Clinical Laboratory Tests, 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

3. B.E. Statland, Clinical Decision Levels for Lab Tests (Oradell, NJ: Medical Economic Books, 1987).

4. NCCLS. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline.* NCCLS document EP9-A [ISBN 1-56238-283-7]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 1995.

5. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method-Comparison Analysis," Clinical Chemistry 25:3, 432 (1979).

6. NCCLS. *Interference Testing in Clinical Chemistry; Proposed Guideline.* NCCLS document EP7-P [ISBN 1-56238-020-6]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 1986.

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CHLORIDE/CL

Chloride is measured by ion-selective electrode potentiometry. In the calculation of results for chloride, concentration is related to potential through the Nernst equation. The performance characteristics of the sensors are equivalent in all cartridge configurations.

The i-STAT System uses direct (undiluted) electrochemical methods. Values obtained by direct methods may differ from those obtained by indirect (diluted) methods.[1]

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels in vivo.[2] If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for chloride, as part of the i-STAT System, is intended for use in the in vitro quantification of arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for measurement of specific analytes and a buffered aqueous calibrant solution of known concentrations. For cartridges that contain a sensor for the measurement of chloride, the calibrant solution contains 100 mmol/L of chloride.

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range[3]
Chloride/CL	mmol/L(mEq/L)	65 – 140	98 – 109

i-STAT measurements are performed on whole blood specimens. The i-STAT System has been calibrated to agree with standard laboratory and reference methods typically performed on serum or plasma. Therefore, the reference ranges presented above are equivalent to reference ranges derived from serum or plasma measurements with standard laboratory methods.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

*The i-STAT System can be configured with the preferred units.

Clinical Significance

Tests for chloride in the blood are important in the diagnosis and treatment of patients suffering from hypertension, renal failure or impairment, cardiac distress, disorientation, dehydration, nausea and diarrhea. Some causes of increased values for chloride include prolonged diarrhea, renal tubular disease, hyperparathyroidism and dehydration. Some causes for decreased values for chloride include prolonged vomiting, burns, salt-losing renal disease, overhydration and thiazide therapy.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below. Method comparison data were collected using NCCLS guideline EP9-A4. Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on comparative methods within 20 minutes of collection.

Deming regression analysis[5] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Interference studies were based on NCCLS guideline EP7.[6]

* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[4] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (mmol/L or mEq/L)

Aqueous Control	Mean	SD	%CV
Level 1	78.7	0.76	1.0
Level 3	105.8	0.80	0.8

Method Comparison (mmol/L or mEq/L)

	Beckman Synchron CX®3	Kodak Ektachem™ 700	Nova STAT Profile® 5
n	189	142	192
Sxx	1.27	0.41	0.89
Syy	0.88	0.90	0.88
Slope	0.99	0.88	0.93
Int't	-0.82	14.6	4.3
Sy.x	1.65	1.84	2.33
Xmin	.93	.63	.96
Xmax	1.14	1.28	1.17
r	0.817	0.914	0.752

Factors Affecting Results*

Thiocyanate may cause the chloride sensor to "star-out". Thiocyanate is a degradation product of nitroprusside treatment and also a product of thiosulphate treatment of cyanide poisoning.

Interferent	Effect
Salicylate	4 mmol/L salicylate will increase chloride results by 3 mmol/L.
Bromide	12.5 mmol/L (100 mg/dL) bromide will increase chloride results by 30 mmol/L.
Lactate	11 mmol/L (100 mg/dL) lactate will increase chloride results by 3.5 mmol/L.
ß-hydroxybutyrate	16 mmol/L (166 mg/dL) b-hydroxybutyrate will increase chloride results by 6 mmol/L.

*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

References

1. N.W. Tietz, E.L. Pruden, O. Siggaard-Andersen, "Electrolytes " in Tietz Textbook of Clinical Chemistry—Second Edition, C.A. Burtis and E.R. Ashwood, eds. (Philadelphia: W.B. Saunders Company, 1994).

2. D.S. Young, Effects of Drugs on Clinical Laboratory Tests, 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

3. B.E. Statland, Clinical Decision Levels for Lab Tests (Oradell, NJ: Medical Economic Books, 1987).

4. NCCLS. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline.* NCCLS document EP9-A [ISBN 1-56238-283-7]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 1995.

5. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method-Comparison Analysis," Clinical Chemistry 25:3, 432 (1979).

6. NCCLS. *Interference Testing in Clinical Chemistry; Proposed Guideline.* NCCLS document EP7-P [ISBN 1-56238-020-6]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 1986.

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Urea is hydrolyzed to ammonium ions in a reaction catalyzed by the enzyme urease.

$$\text{Urea} + H_2O + 2H^+ \xrightarrow{\text{urease}} 2NH^+_4 + CO_2$$

The ammonium ions are measured by an ion-selective electrode. In the calculation of results for urea, concentration is related to potential through the Nernst Equation. The performance characteristics of the sensors are equivalent in all cartridge configurations.

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for urea nitrogen, as part of the i-STAT System, is intended for use in the *in vitro* quantification of arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for measurement of specific analytes and a buffered aqueous calibrant solution of known concentrations. For cartridges that contain a sensor for the measurement of urea nitrogen, the calibrant solution contains 11.2 mg/dL of urea nitrogen (4 mmol/L urea).

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range[2]
Urea Nitrogen/BUN	mg/dL	3 – 140	8 – 26
Urea	mmol/L	1 – 50	2.9 – 9.4
Urea	mg/dL	6 – 300	17 - 56

*The i-STAT System can be configured with the preferred units.

To convert a BUN result in mg/dL to a urea result in mmol/L, multiply the BUN result by 0.357. To convert a urea result in mmol/L to a urea result in mg/dL, multiply the mmol/L result by 6.

i-STAT measurements are performed on whole blood specimens. The i-STAT System has been calibrated to agree with standard laboratory and reference methods typically performed on serum or plasma. Therefore, the reference ranges presented above are equivalent to reference ranges derived from serum or plasma measurements with standard laboratory methods.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

An abnormally high level of urea nitrogen in the blood is an indication of kidney function impairment or failure. Some other causes of increased values for urea nitrogen include prerenal azotemia (e.g. shock), postrenal azotemia, GI bleeding and a high protein diet. Some causes of decreased values for urea nitrogen include pregnancy, severe liver insufficiency, overhydration and malnutrition.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below. Method comparison data were collected using NCCLS guideline EP9-A[3]. Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on comparative methods within 20 minutes of collection.

Deming regression analysis[4] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Interference studies were based on NCCLS guideline EP7.[5]

* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[3] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (mg/dL)

Aqueous Control	Mean	SD	%CV
Level 1	4.3	0.40	9.4
Level 3	66.5	2.16	3.2

Method Comparison (mg/dL)

	Beckman Synchron CX®3	Kodak Ektachem™ 700
n	189	142
Sxx	0.57	0.46
Syy	0.96	0.86
Slope	0.98	0.98
Int't	0.10	-0.28
Sy.x	1.47	1.73
Xmin	3.0	3.0
Xmax	1.15	1.38
r	0.997	0.996

Cartridge Comparison

The performance characteristics of the sensors are equivalent in all cartridge configurations. System difference analysis was performed on 40 patient samples using the i-STAT 6+ and i-STAT EC8+ cartridges. In the 25–60 mg/dL range the average difference was -1.13. In the 60–140 mg/dL range the average difference was -0.77.

Factors Affecting Results*

Endogenous ammonium ions will not affect results.

It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

Interferent	Effect
Thiocyanate	Thiocyanate can cause falsely decreased BUN/urea results on the i-STAT System. Preliminary studies indicated that 140 mg/dL (24 mmol/L) thiocyanate decreased BUN/urea results from 11.8 to 9.3 mg/dL (4.2 to 3.3 mmol/L), approximately 21%. Thiocyanate is a degradation product of nitroprusside treatment and also a product of thiosulphate treatment of cyanide poisoning.

References

1. D.S. Young, *Effects of Drugs on Clinical Laboratory Tests,* 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

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GLUCOSE/GLU

Glucose is measured amperometrically. Oxidation of glucose, catalyzed by the enzyme glucose oxidase, produces hydrogen peroxide (H_2O_2). The liberated hydrogen peroxide is oxidized at the electrode to produce a current which is proportional to the sample glucose concentration. The performance characteristics of the sensors are equivalent in all cartridge configurations.

$$\beta\text{-D-glucose} + H_2O + O_2 \xrightarrow{\text{glucose oxidase}} \text{D-gluconic acid} + H_2O_2$$

$$H_2O_2 \longrightarrow 2H^+ + O_2 + 2e^-$$

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1] If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for glucose, as part of the i-STAT System, is intended for use in the *in vitro* quantification of arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for measurement of specific analytes and a buffered aqueous calibrant solution of known concentrations. For cartridges that contain a sensor for the measurement of glucose, the calibrant solution contains 127 mg/dL (6.99 mmol/L) of glucose.

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range[2]
Glucose/Glu	mg/dL	20 – 700	70 – 105
(fasting)	mmol/L	1.1 – 38.9	3.9 – 5.8
	g/L	0.20-7.00	0.70-1.05

To convert a result from mg/dL to mmol/L, multiply the mg/dL value by 0.055.

i-STAT measurements are performed on whole blood specimens. The i-STAT System has been calibrated to agree with standard laboratory and reference methods typically performed on serum or plasma. Therefore, the reference ranges presented above are equivalent to reference ranges derived from serum or plasma measurements with standard laboratory methods.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

*The i-STAT System can be configured with the preferred units.

Clinical Significance

Glucose is a primary energy source for the body and the only source of nutrients for brain tissue. Measurements for determination of blood glucose levels are important in the diagnosis and treatment of patients suffering from diabetes and hypoglycemia. Some causes for increased values of glucose include diabetes mellitus, pancreatitis, endocrine disorders (e.g. Cushing's syndrome), drugs (e.g. steroids, thyrotoxicosis), chronic renal failure, stress, or I.V. glucose infusion. Some causes of decreased values of glucose include insulinoma, adrenocortical insufficiency, hypopituitarism, massive liver disease, ethanol ingestion, reactive hypoglycemia, and glycogen storage disease.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected at multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using NCCLS guideline EP9-A[3]. Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on comparative methods within 20 minutes of collection.

Deming regression analysis[4] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Interference studies were based on NCCLS guideline EP7.[5]

* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[3] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (mg/dL)

Aqueous Control	Mean	SD	%CV
Level 1	214.5	6.74	3.1
Level 3	55.3	1.43	2.6

Method Comparison (mg/dL)

	Beckman Synchron CX®3	Kodak Ektachem™ 700	Nova STAT Profile® 5
n	189	142	192
Sxx	3.52	0.93	2.88
Syy	7.79	6.65	7.79
Slope	1.07	1.05	1.16
Int't	-6.69	-5.53	-19.83
Sy.x	11.17	9.64	16.08
Xmin	60	52	65
Xmax	450	450	425
r	0.989	0.992	0.977

Cartridge Comparison

System difference analysis was performed on 40 patient samples using the i-STAT 6+ and i-STAT EC4+ cartridges. In the 100–200 mg/dL range the average difference was 1.77. In the 200–300 mg/dL range the average difference was 3.7.

Factors Affecting Results*

Glucose values will decrease in whole blood samples over time. Venous blood glucose is as much as 7 mg/dL less than capillary blood glucose as a result of tissue utilization.[6]

*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

Interferent	Effect
Bromide	12.5mmol/L (100 mg/dL) bromide will decrease glucose results by 30 mg/dL.
pH	Values below 7.4 at 37°C decrease results by approximately 0.9 mg/dL (0.05 mmol/L) per 0.1 pH units. Values above 7.4 at 37°C increase results by approximately 0.8 mg/dL (0.04 mmol/L) per 0.1 pH units.
Hydroxyurea (Droxia®, Hydrea®)	Hydroxyurea may cause significant errors in the measurement of glucose with the i-STAT System. Use an alternative method to measure glucose when patients have been administered hydroxyurea. See note (1) below for typical uses of this drug and note (2) below for details of the interference.
Thiocyanate	Thiocyanate can cause falsely low glucose results on the i-STAT System. Preliminary studies indicated that 24 mmol/L (140 mg/dL) thiocyanate decreased glucose results from 85.6 to 65.8 mg/dL (4.75 to 3.65 mmol/L), approximately 23%. Thiocyanate is a degradation product of nitroprusside treatment and also a product of thiosulphate treatment of cyanide poisoning.
PO_2	Oxygen levels of less than 20 mmHg (2.66 kPa) at 37°C may decrease results.

*It is possible that other interfering substance may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

Notes:

1) Hydroxyurea is a DNA synthesis inhibitor used in the treatment of various forms of cancer, sickle cell anemia, and HIV infection. This drug is used to treat malignancies including melanoma, metastatic ovarian cancer, and chronic myelogenous leukemia. It is also used in the treatment of polycythemia vera, thrombocytopenia, and psoriasis. At typical doses ranging from 500 mg to 2 g/day, concentrations of hydroxyurea in patients' blood may be sustained at approximately 100 to 500 µmol/L. Higher concentrations may be observed soon after dosing or at higher therapeutic doses.

2) For every 100 µmol/L hydroxyurea in the whole blood sample, glucose will be increased by approximately 8 mg/dL (0.44 mmol/L), up to a whole blood hydroxyurea concentration of at least 921 µmol/L (maximum concentration tested). The magnitude of the bias is independent of the glucose level over a range of at least 75 mg/dL (4.2 mmol/L) to 645 mg/dL (35.8 mmol/L).

Ascorbic acid up to 0.63 mmol/L (11 mg/dL), uric acid up to 12 mg/dL, lactate up to 11 mmol/L (100 mg/dL), β-hydroxybutyrate up to 16mmol/L (166mg/dL), acetoacetate up to 10mmol/L (100 mg/dL), acetaminophen up to 1.32 mmol/L (20 mg/dL) and hematocrit levels between 15–75 %PCV were tested and found not to interfere with glucose results.

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1. D.S. Young, Effects of Drugs on Clinical Laboratory Tests, 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

2. P.C. Painter, J.Y. Cope, J.L. Smith, "Reference Ranges, Table 41-20" in Tietz Textbook of Clinical Chemistry—Second Edition, C.A. Burtis and E.R. Ashwood, eds. (Philadelphia: W.B. Saunders Company, 1994).

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HEMATOCRIT/HCT AND CALCULATED HEMOGLOBIN/HB

Hematocrit is determined conductometrically. The measured conductivity, after correction for electrolyte concentration, is inversely related to the hematocrit. The performance characteristics of the sensors are equivalent in all cartridge configurations.

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for hematocrit, as part of the i-STAT System, is intended for use in the *in vitro* quantification of arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for measurement of specific analytes and a buffered aqueous calibrant solution of known concentrations and known conductance.

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range[2]
Hematocrit/Hct	%PCV	10 – 75	38 – 51**
	Fraction	0.10 – 0.75	0.38 – 0.51
Hemoglobin/Hb	g/dL	3 – 26	12 – 17
	g/L	34 – 255	120 – 170
	mmol/L	2 – 16	7 – 11

*The i-STAT System can be configured with the preferred units.

** The reference ranges for hematocrit and hemoglobin span both female and male populations.

To convert a result from % PCV to fraction packed cell volume, divide the % PCV result by 100. For the measurement of hematocrit, the i-STAT System can be customized to agree with methods using either K_3EDTA or methods using K_2EDTA or NaEDTA as an anticoagulant. The default calibration is for K_3EDTA. While NaEDTA and K_2EDTA are recommended by NCCLS[3], K_3EDTA is currently the most popular anticoagulant despite the fact that mean cell volumes are decreased by approximately 4%.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

Hematocrit is a measurement of the volume of red blood cells. This is a key indicator of the body's state of hydration, anemia or severe blood loss, as well as the blood's ability to transport oxygen. Some causes of increased values of hematocrit include dehydration, burns, impaired ventilation and renal disorders. Some causes for decreased values of hematocrit include hemolytic anemias, iron deficiency, marrow depression or blood loss.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below. Method comparison data were collected using NCCLS guideline EP9-A[4]. Venous blood samples, collected in lithium heparin Vacutainer® tubes, were analyzed in duplicate on the i-STAT System and on the comparative methods for hematocrit within 20 minutes of collection.

Deming regression analysis[5] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Interference studies were based on NCCLS guideline EP7.[6]

* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[5] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (%PCV)

Whole Blood Control	Mean	SD	%CV
Low	29.9	0.68	2.3
High	49.8	1.00	2.0

Method Comparison (%PCV)

	Coulter® S Plus	Technicon™ H-1	Nova STAT Profile® 5
n	142	182	192
Sxx	0.50	0.50	0.46
Syy	1.09	1.30	1.31
Slope	0.98	1.09	1.06
Int't	1.78	-3.02	-3.98
Sy.x	2.03	2.32	2.063
Xmin	.18	.21	.21
Xmax	.51	.50	.50
r	0.952	0.910	0.932

Factors Affecting Results*

Interferent	Effect
WBC	Grossly elevated white blood cell counts may increase results.
Total Protein	Hematocrit results are affected by the level of total protein as follows:

Displayed Result	TP < 6.5 g/dL	TP > 8.0 g/dL
HCT < 40 %PCV	Hct decreased by 1% PCV for each decrease of 1 g/dL TP	Hct increased by 1%PCV for each increase 1 g/dL TP
HCT > 40 % PCV	Hct decreased by 0.75 % PCV for each decrease of 1 g/dL TP	Hct increased by 0.75 %PCV for each increase 1 g/dL TP

Total protein can be lower than the adult reference range in neonates, burn patients, and in patients on cardiopulmonary bypass pump. The CPB sample type can be used to correct for the dilutional affect of pump fluid during and immediately after cardiopulmonary bypass surgery.

Lipids	Abnormally high lipids may increase results. Interference from lipids will be about two thirds the size of the interference from protein.

*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

Cartridge Comparison

The performance characteristics of the sensors are equivalent in all cartridge configurations. System difference analysis was performed on 40 patient samples using the i-STAT 6+ and i-STAT E3+ cartridges. In the 15–30 %PCV range the average difference was 0.462. In the 30–50 %PCV range the average difference was 0.097.

Calculated Result for Hemoglobin

The i-STAT System provides a calculated hemoglobin result which is determined as follows[7]:

hemoglobin (g/dL) = hematocrit (decimal fraction) x 34

To convert a hemoglobin result from g/dL to mmol/L, multiply the displayed result by 0.621. The calculation of hemoglobin from hematocrit assumes a normal MCHC.

References

1. D.S. Young, Effects of Drugs on Clinical Laboratory Tests, 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

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IONIZED CALCIUM/ICA

Ionized calcium is measured by ion-selective electrode potentiometry. In the calculation of results for ionized calcium concentration is related to potential through the Nernst equation. Results are measured at 37°C using cartridges that require thermal control and are corrected to 37°C using cartridges that do not require thermal control. The performance characteristics of the sensors are equivalent in all cartridge configurations.

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for ionized calcium, as part of the i-STAT System, is intended for use in the *in vitro* quantification of arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for measurement of specific analytes and a buffered aqueous calibrant solution of known concentrations. For cartridges that contain a sensor for the measurement of ionized calcium, the calibrant solution contains 1.25 mmol/L of ionized calcium.

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range[2]
Ionized Calcium/iCa	mmol/L	0.25 – 2.50	1.12 – 1.32
	mg/dL	1.0 – 10.0	4.5 – 5.3

To convert a result from mmol/L to mg/dL, multiply the mmol/L value by 4. To convert mmol/L to mEq/L multiply the mmol/L value by 2

For the measurement of ionized calcium, the i-STAT System has been calibrated to agree with standard direct electrochemical methods performed on whole blood.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

*The i-STAT System can be configured with the preferred units.

Clinical Significance

Although most of the calcium in blood is bound to protein or complexed to smaller anionic species, the biologically active fraction of calcium is free ionized calcium. Through its role in a number of enzymatic reactions and in membrane transport mechanisms, ionized calcium is vitally important in blood coagulation, nerve conduction, neuromuscular transmission and in muscle contraction. Increased ionized calcium (hypercalcemia) may result in coma. Other symptoms reflect neuromuscular disturbances, such as hyperreflexia and/or neurologic abnormalities such as neurasthenia, depression or psychosis. Decreased ionized calcium (hypocalcemia) often results in cramps (tetany), reduced cardiac stroke work and depressed left ventricular function. Prolonged hypocalcemia may result in bone demineralization (osteoporosis) which can lead to spontaneous fractures. Measurements of ionized calcium have proven of value under the following clinical conditions: transfusion of citrated blood, liver transplantation, open heart surgery, neonatal hypocalcemia, renal disease, hyperparathyroidism, malignancy, hypertension and pancreatitis.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below. Method comparison data were collected using NCCLS guideline EP9-A[3]. Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System and on the comparative methods within 10 minutes of each other.

Deming regression analysis[4] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Interference studies were based on NCCLS guideline EP7.[5]

* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[3] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (mmol/L)

Aqueous Control	Mean	SD	%CV
Level 1	1.56	0.018	1.14
Level 3	0.76	0.012	1.56

Method Comparison (mmol/L)

	Radiometer ICA1	Nova STAT Profile
n	47	57
Sxx	0.009	0.017
Syy	0.017	0.017
Slope	0.925	0.960
Int't	0.113	0.062
Sy.x	0.035	0.029
Xmin	0.46	0.53
Xmax	2.05	2.05
r	0.982	0.982

Factors Affecting Results*

Venous stasis (prolonged tourniquet application) and forearm exercise may increase ionized calcium due to a decrease in pH caused by localized production of lactic acid[6]. Exposing the sample to air will cause an increase in pH due to the loss of CO_2 which will decrease ionized calcium.

Heparin binds calcium. Each unit of heparin added per mL of blood will decrease ionized calcium by 0.01 mmol/L.[6] Therefore, the correct ratio of heparin anticoagulant to blood must be achieved during sample collection. Intravenous injection of 10,000 units of heparin has been shown in adults to cause a significant decrease of ionized calcium of about 0.03 mmol/L.[6]

Interferent	Effect
Magnesium	1.0 mmol/L magnesium above normal will increase ionized calcium results by 0.04 mmol/L.

It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

References

1. D.S. Young, Effects of Drugs on Clinical Laboratory Tests, 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

2. P.C. Painter, J.Y. Cope, J.L. Smith, "Reference Ranges, Table 41–20" in Tietz Textbook of Clinical Chemistry—Second Edition, C.A. Burtis and E.R. Ashwood, eds. (Philadelphia: W.B. Saunders Company, 1994).

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PO_2 AND CALCULATED OXYGEN SATURATED (sO_2)

PO_2 is measured amperometrically. The oxygen sensor is similar to a conventional Clark electrode. Oxygen permeates through a gas permeable membrane from the blood sample into an internal electrolyte solution where it is reduced at the cathode. The oxygen reduction current is proportional to the dissolved oxygen concentration. The performance characteristics of the sensors are equivalent in all cartridge configurations.

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for PO_2, as part of the i-STAT System, is intended for use in the *in vitro* quantification of arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge configuration with sensors for the measurement of pH, PCO_2 and PO_2 contains heating elements, one reference electrode, sensors for measurement of specific analytes, and a buffered aqueous calibrant solution of known concentrations. For cartridges that contain a sensor for the measurement of oxygen, the calibrant solution contains approximately 160 mmHg (21.28 kPa) of PO_2 which is equilibrated to atmospheric PO_2 during the calibration cycle.

Expected Values

Test	Units*	Reportable Range	Reference Range[2]
PO_2	mmHg	5 – 800	80 – 105
	kPa	0.7 – 106.6	10.7 – 14.0
sO_2**	%	not applicable	95 – 98

*The i-STAT System can be configured with the preferred units.

** Calculated

To convert PO_2 results from mmHg to kPa, multiply the mmHg value by 0.133.

The i-STAT System has been calibrated to agree with standard blood gas methods for pH, PCO_2 and PO_2 performed on arterial whole blood. Therefore, the reference ranges listed above for the i-STAT measurements are equivalent to reference ranges published in the literature. The reference ranges shown are for a healthy population. Interpretation of blood gas measurements depend on the underlying condition (eg. patient temperature, ventilation, posture and circulatory status).

Clinical Significance

PO_2 (partial pressure of oxygen) is a measurement of the tension or pressure of oxygen dissolved in blood. Some causes for decreased values of PO_2 include decreased pulmonary ventilation (e.g. airway obstruction or trauma to the brain), impaired gas exchange between alveolar air and pulmonary capillary blood (e.g. bronchitis, emphysema, or pulmonary edema), and alteration in the flow of blood within the heart or lungs (e.g. congenital defects in the heart or shunting of venous blood into the arterial system without oxygenation in the lungs).

sO_2 (oxygen saturation) is the amount of oxyhemoglobin expressed as a fraction of the total amount of hemoglobin able to bind oxygen (oxyhemoglobin plus deoxyhemoglobin).

$$sO_2 = 100 \frac{(X^3 + 150X)}{X^3 + 150X + 23400}$$

$$\text{where } X = PO2 * 10^{(0.48(pH-7.4)-0.0013(HCO3-25))}$$

sO_2 is calculated from measured PO_2, PCO_2 and pH. However, this calculation assumes normal affinity of oxygen for hemoglobin (it does not take into consideration extracellular erythrocyte diphosphoglycerate (2,3-DPG) concentrations which affect the oxyhemoglobin dissociation curve) and assumes that normal amounts of disfunctional hemoglobin (carboxy-, met- and sulfhemoglobin) are present. Oxygen saturation is a useful predictor of the amount of oxygen that is available for tissue perfusion. Some causes for decreased values of sO_2 include low PO_2 or impaired ability of hemoglobin to carry oxygen.

Performance Characteristics

The typical performance data summarized below was collected in a health care facility by health care professionals trained in the use of the i-STAT System and comparative method.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below. Method comparison data were collected using NCCLS guideline EP9-A[6]. Arterial blood samples were collected from hospital patients in 3cc blood gas syringes and were analyzed in duplicate on the i-STAT System and the Radiometer ABL500 within 5 minutes of each other.

Deming regression analysis[4] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.* Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[6] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (mmHg)

Aqueous Control	Mean	SD	%CV
Level 1	65.1	3.12	4.79
Level 3	146.5	6.00	4.10

Method Comparison (mmHg)

	Radiometer ABL500
n	.45
Sxx	3.699
Syy	2.776
Slope	1.023
Int't	-2.560
Sy.x	2.517
r	0.996

Factors Affecting Results*

Exposure of the sample to air will cause an increase in PO_2 when values are below 150 mmHg and a decrease in PO_2 when values are above 150 mmHg (approximate PO_2 of room air).

Standing anaerobically at room temperature will decrease pH at a rate of 0.03 per hour, will increase PCO_2 by approximately 4 mmHg per hour and will decrease PO_2 at a rate of 2–6 mmHg per hour.[5]

Do not ice samples before testing – PO_2 results may be falsely elevated in cold samples. Do not use a cold cartridge – PO_2 results may be falsely decreased if the cartridge is cold.

*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

Factors Affecting Calculated Results

sO_2 values calculated from a measured PO_2 and an assumed oxyhemoglobin dissociation curve may differ significantly from the direct measurement.[6]

References

1. D.S. Young, Effects of Drugs on Clinical Laboratory Tests, 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

2. B.E. Statland, Clinical Decision Levels for Lab Tests (Oradel, NJ: Medical Economic Books, 1987).

3. NCCLS. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline.* NCCLS document EP9-A [ISBN 1-56238-283-7]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 1995.

4. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method-Comparison Analysis," Clinical Chemistry 25:3, 432 (1979).

5. E.L. Pruden, O. Siggaard-Andersen, and N.W. Tietz, "Blood Gases and pH," in Tietz Textbook of Clinical Chemistry—Second Edition, C.A. Burtis and E.R. Ashwood, eds. (Philadelphia: W.B. Saunders Company, 1994).

6. NCCLS. *Blood Gas and pH Analysis and Related Measurements; Approved Guideline.* NCCLS document C46-A [ISBN 1-56238-444-9]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2001.

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pH is measured by direct potentiometry. In the calculation of results for pH, concentration is related to potential through the Nernst equation. Results are reported at 37°C. The performance characteristics of the sensors are equivalent in all cartridge configurations.

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for pH, as part of the i-STAT System, is intended for use in the *in vitro* quantification of arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for measurement of specific analytes and a buffered aqueous calibrant solution of known concentrations. For cartridges that contain a sensor for the measurement of pH, the calibrant solution is buffered to 7.43.

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range	
pH		6.50 – 8.00	7.35 – 7.45[2] (arterial)	7.31 – 7.41** (venous)

*The i-STAT System can be configured with the preferred units.
** Calculated from Siggaard-Andersen nomogram.

Venous samples normally measure 0.01 – 0.03 pH units lower than arterial samples.

For the measurement of pH, the i-STAT System has been calibrated to agree with standard blood gas methods performed on whole blood at 37°C.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

pH is an index of the acidity or alkalinity of the blood with an arterial pH of <7.35 indicating an acidemia and >7.45 alkalemia.[3]

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below. Method comparison data were collected using NCCLS guideline EP9-A[4]. Venous blood samples were collected in evacuated tubes and arterial samples were collected in blood gas syringes with lithium heparin anticoagulant. All sample were analyzed in duplicate on the i-STAT System and on the comparative methods within 10 minutes of each other. Arterial blood samples were collected from hospital patients in 3 mL blood gas syringes and were analyzed in duplicate on the i-STAT-System and the Radiometer ABL500 within 5 minutes of each other.

Deming regression analysis[5] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

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* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[4] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data

Aqueous Control	Mean	SD	%CV
Level 1	7.165	0.005	0.08
Level 3	7.656	0.003	0.04

Method Comparison

	IL BGE	Radiometer ICA 1	Nova STAT Profile 5	Radiometer ABL500
n	62	47	57	45
Sxx	0.005	0.011	0.006	0.004
Syy	0.009	0.008	0.008	0.008
Slope	0.974	1.065	1.058	1.0265
Int't	0.196	-0.492	-0.436	-0.1857
Sy.x	0.012	0.008	0.010	0.0136
Xmin	7.210	7.050	7.050	
Xmax	7.530	7.570	7.570	
r	0.985	0.990	0.9920	.986

Factors Affecting Results*

Venous stasis (prolonged tourniquet application) and forearm exercise may decrease pH due to localized production of lactic acid. Exposing the sample to air will cause an increase in pH due to the loss of CO_2. pH decreases on standing anaerobically at room temperature at a rate of 0.03 pH units per hour.[3]

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*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

References

1. D.S. Young, Effects of Drugs on Clinical Laboratory Tests, 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

2. P.C. Painter, J.Y. Cope, J.L. Smith, "Reference Ranges, Table 41–20" in Tietz Textbook of Clinical Chemistry—Second Edition, C.A. Burtis and E.R. Ashwood, eds. (Philadelphia: W.B. Saunders Company, 1994).

3. E.L. Pruden, O. Siggaard-Andersen, and N.W. Tietz, Blood Gases and pH, in Tietz Textbook of Clinical Chemistry, Second Edition, ed. C.A. Burtis and E.R. Ashwood. (Philadelphia: W.B. Saunders Company, 1994.

4. NCCLS. *Interference Testing in Clinical Chemistry; Proposed Guideline.* NCCLS document EP7-P [ISBN 1-56238-020-6]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 1986.

5. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method-Comparison Analysis," Clinical Chemistry 25:3, 432 (1979).

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PCO_2 AND CALCULATED VALUES FOR HCO_3, TCO_2, BASE EXCESS AND ANION GAP

PCO_2 is measured by direct potentiometry. In the calculation of results for PCO_2, concentration is related to potential through the Nernst equation. Results are measured at 37°C when using cartridges that require thermal control and corrected to 37°C when using cartridges that do not require thermal control. The performance characteristics of the sensors are equivalent in all cartridge configurations.

Calculated Values

When a cartridge includes sensors for both pH and PCO_2, bicarbonate (HCO_3), total carbon dioxide (TCO_2) and base excess (BE) can be calculated.[1]

$$\log HCO_3 = pH + \log PCO_2 - 7.608$$

$$TCO_2 = HCO_3 + 0.03\ PCO_2$$

$$BE_{ecf} = HCO_3 - 24.8 + 16.2\ (pH - 7.4)$$

$$BE_b = (1 - 0.014{*}Hb) * [\ HCO_3 - 24.0 + (1.43 * Hb + 7.7) * (pH - 7.4)\ ]$$

When a cartridge includes sensors for sodium, potassium, chloride, pH and PCO_2, anion gap can be calculated.

$$\text{Anion Gap} = (Na + K) - (Cl + HCO_3)$$

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[2] If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for PCO_2, as part of the i-STAT System, is intended for use in the *in vitro* quantification of arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration); sensors for measurement of specific analytes and a buffered aqueous calibrant solution of known concentrations. For cartridges that contain a sensor for the measurement of PCO_2, the calibrant solution contains 30 mmHg (3.99 kPa) PCO_2.

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range	
			(arterial)	(venous)
Partial Pressure Carbon Dioxide/$P\mathrm{CO}_2$	mmHg	5 – 130	35 – 45[3]	41 – 51
	kPa	0.67 – 17.330	4.67 – 6.00	5.47 – 6.80
Bicarbonate/HCO_3	mmol/L	1 – 85	22 – 26**	23 – 28**
Total Carbon Dioxide/TCO_2	mmol/L	1 – 85	23 – 27**	24 – 29**
Base Excess/BE	mmol/L	(-30) – (+30)	(-2) – (+3)[3]	(-2) – (+3)[3]
Anion Gap/AnGap	mmol/L	(-10) – (+99)	10 – 20[3]	10 – 20[3]

*The i-STAT System can be configured with the preferred units.
**Calculated from Siggaard-Andersen nomogram.

For TCO_2, values measured on serum or plasma by chemistry analyzers may be slightly lower than TCO_2 calculated from pH and $P\mathrm{CO}_2$ due to loss of CO_2 during non-anaerobic handling.[5] Up to 6mmol/L CO_2 can be lost per hour by exposure of the sample to air.[6]

To convert $P\mathrm{CO}_2$ results from mmHg to kPa, multiply the mmHg value by 0.133.

For the measurement of $P\mathrm{CO}_2$, the i-STAT System has been calibrated to agree with standard blood gas methods performed on whole blood at 37°C.

The reference ranges programmed into the analyzer and shown above are intended to be used as guides for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

$P\mathrm{CO}_2$ along with pH is used to assess acid-base balance. $P\mathrm{CO}_2$ (partial pressure of carbon dioxide), the respiratory component of acid-base balance, is a measure of the tension or pressure of carbon dioxide dissolved in the blood. $P\mathrm{CO}_2$ represents the balance between cellular production of CO_2 and ventilatory removal of CO_2 and a change in $P\mathrm{CO}_2$ indicates an alteration in this balance. Causes of primary respiratory acidosis (increase in $P\mathrm{CO}_2$) are airway obstruction, sedatives and anesthetics, respiratory distress syndrome, and chronic obstructive pulmonary disease. Causes of primary respiratory alkalosis (decreased $P\mathrm{CO}_2$) are hypoxia (resulting in hyperventilation) due to chronic heart failure, edema and neurologic disorders, and mechanical hyperventilation.

HCO_3 (bicarbonate), the most abundant buffer in the blood plasma, is an indicator of the buffering capacity of blood. Regulated primarily by the kidneys, HCO_3 is the metabolic component of acid-base balance. Causes of primary metabolic acidosis (decrease in HCO_3) are ketoacidosis, lactate acidosis (hypoxia), and diarrhea. Causes of primary metabolic alkalosis (increase in HCO_3) are vomiting and antacid treatment.

TCO_2 (total carbon dioxide) is either measured on plasma by automated chemistry analyzers or is calculated from pH and $P\mathrm{CO}_2$ measured on whole blood gas analyzers. TCO_2 is a measure of carbon dioxide which exists in several states: CO_2 in physical solution or loosely bound to proteins, HCO_3 or CO_3 ions, and carbonic acid ($\mathrm{H}_2\mathrm{CO}_3$). Bicarbonate ions make up all but approximately 2mmol/L of the total carbon dioxide of plasma. Measurement of TCO_2 as part of an electrolyte profile is useful chiefly to evaluate HCO_3 concentration. TCO_2 and HCO_3 are useful in the assessment of acid-base imbalance (along with pH and $P\mathrm{CO}_2$) and electrolyte imbalance.

Base excess of the extracellular fluid or standard base excess is defined as the concentration of titratable base minus the concentration of titratable acid when titrating the average intracellular fluid (plasma plus interstitial fluid) to an arterial plasma pH of 7.40 at $P\mathrm{CO}_2$ of 40 mmHg at 37°C. Excess concentration of base in the average ECF remains virtually constant during acute changes in the PCO_2 and reflects only nonrespiratory component of pH-disturbances.

Anion gap is reported as the difference between the commonly measured cations sodium and potassium and the commonly measured anions chloride and bicarbonate. The size of the gap reflects unmeasured cations and anions and is therefore an analytical gap. Physiologically, a deficit of anions cannot exist. While relatively nonspecific, anion gap is useful for the detection of organic acidosis due to an increase in anions that are difficult to measure. Anion gap can be used to classify metabolic acidosis into high and normal anion gap types. Anion gap may be only slightly increased in diarrhea and renal failure, but elevated (often >25) due to an increase in organic anions in lactic acidosis, ketoacidosis (alcoholic, diabetic, starvation) and uremia, an increase in inorganic anions in uremia, and an increase in anions from drugs such a salicylate and carbenicillin or toxins such as methanol and ethanol.

Performance Characteristics

The typical performance data summarized below was collected in a health care facility by health care professionals trained in the use of the i-STAT System and comparative methods. Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using NCCLS guideline EP9-A[7]. Venous blood samples were collected in blood gas syringes. To measure TCO_2, the sample was centrifuged to obtain plasma. All samples were analyzed in duplicate on the i-STAT System and on the comparative methods within 10 minutes of each other. Arterial blood samples were collected from hospital patients in 3cc blood gas syringes and were analyzed in duplicate on the i-STAT System and the Radiometer ABL500 within 5 minutes of each other.

Deming regression analysis[8] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[7] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (mmHg)

Aqueous Control	Mean	SD	%CV
Level 1	63.0	1.72	2.73
Level 3	19.4	0.70	3.59

Method Comparison (mmHg)

	PCO_2 IL BGE	TCO_2 IL BGE	TCO_2 Beckman CX®3	Radiometer ABL500
n	62	62	51	45
Sxx	0.69	0.40	0.55	0.549
Syy	1.24	0.84	0.55	1.059
Slope	1.003	1.136	1.155	0.958
Int't	-0.8	-4.1	-2.6	1.036
Sy.x	1.65	1.38	1.56	11.460
Xmin	30.4	19.3	18.3	
Xmax	99.0	43.9	36.1	
r	0.989	0.965	0.935	0.995

Factors Affecting Results*

Exposing the sample to air allows CO_2 to escape which causes PCO_2 to decrease and pH to increase and HCO_3 and TCO_2 to be under-estimated. The use of partial-draw tubes (evacuated tubes that are adjusted to draw less than the tube volume, e.g. a 5 mL tube with enough vacuum to draw only 3 mL) is not recommended for use with the i-STAT System because of the potential for decreased measured PCO_2 results and calculated HCO_3 and TCO_2 values. Under-filling blood collection tubes may also cause decreased PCO_2 results. Care must also be taken to eliminate "bubbling" of the sample with a pipette when filling a cartridge to avoid the loss of CO_2 in the blood.

Allowing blood to stand (without exposure to air) before testing allows PCO_2 to increase and pH to decrease, which will cause HCO_3 and TCO_2 to be over-estimated, due to metabolic processes.

Caution: When using either SIMS Portex Dry Line Draw arterial blood gas sampling syringes with dry lithium heparin or SIMS Portex Anaerobic Line Draw arterial blood gas sampling syringes with liquid sodium heparin with the i-STAT System, ensure that the lot number is 107xxx or higher. Lots below 107xxx have a potential for causing sporadic, artificially low PCO_2 results on the i-STAT System when measuring blood collected with these syringes. SIMS Portex Pro-Vent® syringes and Pulsator® syringes have always been compatible with the i-STAT System. For questions regarding the use of SIMS syringes with the i-STAT System, contact SIMS Portex, Inc., at the USA phone number 603-352-3812 (country code 1) and identify yourself as an i-STAT System user.

Interferent	Effect
Propofol (Diprivan®)	Procedures that involve sustained (>1hour) administration of propofol at rates in excess of 50 µg/kg/min (3 mg/kg/hour) may result in significant errors in i-STAT PCO_2 results (see Note 1 below). Alternately, such administration may result in the automated suppression of PCO_2 and pH values (*** displayed) by the analyzer's quality system. Use an alternative method to measure PCO_2 when administering propofol at rates in excess of this level. Consider an alternative method when administering propofol at any sustained rate to patients with renal impairment. See Note 3 for an alternative offered by i-STAT.

Thiopental Sodium	Sustained administration (over more than a few minutes) of thiopental sodium, either by continuous or intermittent drips, may result in plasma concentrations of thiopental sodium that yield significant errors in i-STAT $P\text{CO}_2$ results (see Note 2 below). Alternately, such administration may result in the automated suppression of $P\text{CO}_2$ and pH values (*** displayed) by the analyzer's quality system. Use an alternate method to measure $P\text{CO}_2$ when administering thiopental sodium on a sustained basis. See Note 3 for an alternative offered by i-STAT.

*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

Notes:

1) Propofol is an intravenous sedative-hypnotic agent. Among its applications are the induction and maintenance of anesthesia and the sedation of intubated, mechanically ventilated patients. Although propofol itself does not directly interfere with the measurement of $P\text{CO}_2$ on the i-STAT System, decreases in $P\text{CO}_2$ of > 5 mmHg (0.67 kPa) have been observed on some patients due to metabolic byproducts of propofol, as a result of sustained (>1hr) administration at rates in excess of 50 µg/kg/min (3 mg/kg/hour). At doses of 50-100 µg/kg/min (3-6mg/kg/hour) some errors as large as 10 mmHg or 1.33 kPa.(below 40 mmHg or 5.33 kPa) or 25% (above 40 mmHg or 5.33 kPa) were observed. At doses significantly above 100 µg/kg/min (6 mg/kg/hour) we have observed errors as large as 40% for administration in excess of 5 hours, although more typically results were suppressed by the analyzer (***displayed). Below 50 µg/kg/min, decreases are typically less than 3 mmHg but sometimes as large as 5 mmHg (0.67 kPa). We have observed no decreases when a single dose of propofol is administered to induce anesthesia. We advise caution, however, when administering propofol to any patient with renal impairment as this may affect the clearance rate of metabolic byproducts.

2) Thiopental Sodium (*syn.* thiomebumal sodium, penthiobarbital sodium, thiopentone sodium, thionembutal, Pentothal Sodium®, Nesdonal Sodium®, Intraval Sodium®, Trapanal®, and Thiothal Sodium[9]) is an ultra-short-acting, intravenous anesthetic. It is used as an induction agent for general anesthesia, to control status epilepticus, in the treatment of intracranial hypertension, and in narcoanalysis of psychiatric disorders. Sustained administration (over more than a few minutes) of thiopental sodium may lead to >5 mmHg (0.67 kPa) decreases in $P\text{CO}_2$ results. Errors observed on patient samples have been as large as 20 mmHg (2.67 kPa). For single dose administration of thiopental given over a few minutes, such as in the induction of anesthesia, interference on the i-STAT $P\text{CO}_2$ is modest (<10% at 40 mmHg or 5.33 kPa, <15% at 70 mmHg or 9.33 kPa) approximately 15 minutes after administration of typical doses, since thiopental is rapidly absorbed from the bloodstream, falling below 10 µg/mL within 15 minutes[10]. The interference will continue to diminish as the drug continues to be absorbed.

(3) The interference affects cited above refer to the expected i-STAT System performance using analyzers with **standard software**:

- JAMSxxx with CLEW Axx in the i-STAT Portable Clinical Analyzer (except Japan), i-STAT 1 Analyzer and i-STAT 300F Analyzer. ('x' indicates any alphanumeric character.)
- JAMSxxx with CLEW Cxx in the i-STAT Portable Clinical Analyzer in Japan.
- HPxxxxx with CLEW Hxx (Jxx in Japan) in the Philips Medical System Blood Analysis Module.

i-STAT offers an **alternative version** of software that reduces the interference effect of propofol and thiopental by about 2.5 times relative to that observed with the standard software.

- MINTxxx with CLEW Dxx in the i-STAT Portable Clinical Analyzer (except Japan), i-STAT 1 Analyzer and i-STAT 300F Analyzer. ('x' indicates any alphanumeric character.)
- MINTxxx with CLEW Exx in the i-STAT Portable Clinical Analyzer in Japan.
- MNxxxxx with CLEW Nxx (Vxx in Japan) in the Philips Medical Systems Blood Analysis Module.

Software version MINTxxx/Dxx (or MNxxxxx/Nxx) reduces interference effects by reducing the temperature of the $P\mathrm{CO}_2$ measurement from 37°C to 30°C. When MINTxxx or MNxxxxx is in use, all references in the i-STAT product literature to sensor, test, or cartridge temperature control to 37°C should be interpreted to indicate temperature control of $P\mathrm{CO}_2$ and pH measurements to 30°C (all other analytes are measured as they are in the standard software). The reported $P\mathrm{CO}_2$ and pH results have been corrected to their 37°C values. When using this software, the following interference affects are observed:

Interferent	**Effect (Software version MINTxxx/Dxx/Exx or MNxxxxx/Nxx/Vxx only)**
Propofol (Diprivan®)	Sustained administration of propofol over >5 hours at rates in excess of 90 µg/kg/min (5.4 mg/kg/hour) may result in significant errors (>5 mmHg or 0.67 kPa) in i-STAT $P\mathrm{CO}_2$ results. Alternately, such administration may result in the automated suppression of $P\mathrm{CO}_2$ and pH results (*** displayed) by the analyzer's quality system. Consider an alternate method when administering propofol at rates in excess of this level. Use caution in the interpretation of results or consider an alternate method to measure $P\mathrm{CO}_2$ when administering propofol at any sustained rate to patients with renal impairment.
Thiopental Sodium	Sustained administration (over more than a few minutes) of thiopental sodium, either by continuous or intermittent drips, may result in plasma concentrations of thiopental sodium that yield significant errors (>5 mmHg or 0.67 kPa) in i-STAT $P\mathrm{CO}_2$ results. Alternately, such administration may result in the automated suppression of $P\mathrm{CO}_2$ and pH results (*** displayed) by the analyzer's quality system. For single dose administration over a few minutes, such as in the induction of anesthesia, interference is modest (<4% at 40 mmHg or 5.33 kPa, <6% at 70 mmHg or 9.33 kPa) approximately 15 minutes after administration of typical doses. Use caution in the interpretation of results or consider an alternate method to measure $P\mathrm{CO}_2$ when administering thiopental sodium on a sustained basis.

When using the alternate software, **the analyzer operating temperature range for running cartridges is restricted to 16-28°C**, instead of the standard 16-30°C as stated in the product literature. With the exception of this and the interference characteristics stated above, the i-STAT System with the alternative MINTxxxx/Dxx or MNxxxx/Nxx software version is equivalent to that of the standard system. To facilitate management of the i-STAT System when both versions of software are used in a single facility, note that the software version in an analyzer is displayed on the status page of the analyzer. The CLEW version is on printouts from the handheld analyzer and is also transmitted to the i-STAT Central Data Station and stored in the database.

References

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CREATININE/CREA

Creatinine is hydrolyzed to creatine in a reaction catalyzed by the enzyme creatinine amidohydrolase. Creatine is then hydrolyzed to sarcosine in a reaction catalyzed by the enzyme creatine amidinohydrolase. The oxidation of sarcosine, catalyzed by the enzyme sarcosine oxidase, produces hydrogen peroxide (H_2O_2). The liberated hydrogen peroxide is oxidized at the platinum electrode to produce a current which is proportional to the sample creatinine concentration.

$$\text{Creatinine} + H_2O \xrightarrow{\text{Creatinine Amidohydrolase}} \text{Creatine}$$

$$\text{Creatine} + H_2O \xrightarrow{\text{Creatine Amidinohydrolase}} \text{Sarcosine} + \text{Urea}$$

$$\text{Sarcosine} + O_2 + H_2O \xrightarrow{\text{Sarcosine Oxidase}} \text{Glycine} + \text{Formaldehyde} + H_2O_2$$

$$H_2O_2 \longrightarrow O_2 + 2H^+ + 2e^-$$

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo.*[1] If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

INTENDED USE

The test for creatinine, as part of the i-STAT System, is intended for use in the *in vitro* quantification of creatinine in arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for measurement of specific analytes and a buffered aqueous calibrant solution of known concentrations. For cartridges that contain a sensor for the measurement of creatinine, the calibrant solution contains 2.2 mg/dL (194 µmol/L) of creatinine.

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range
Creatinine/Crea	mg/dL	0.2 – 20.0	0.6 – 1.3[2]
	µmol/L	18 – 1768	53 – 115

To convert a creatinine result from mg/dL to µmol/L, multiply the mg/dL value by 88.4.

i-STAT measurements are performed on whole blood specimens. The i-STAT System has been calibrated to agree with standard laboratory and reference methods typically performed on serum and plasma. Therefore, the reference ranges presented above are equivalent to reference ranges derived from serum or plasma measurements with standard laboratory methods.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

* The i-STAT System can be configured with the preferred units.

Clinical Significance

Elevated levels of creatinine are mainly associated with abnormal renal function and occur whenever there is a significant reduction in glomerular filtration rate or when urine elimination is obstructed.

The concentration of creatinine is a better indicator of renal function than urea or uric acid because it is not affected by diet, exercise, or hormones.

The creatinine level has been used in combination with BUN to differentiate between prerenal and renal causes of an elevated urea/BUN.

Performance Characteristics

The typical performance data summarized below were collected in health care facilities by professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected using NCCLS guideline EP5-A[3]. Duplicates of each level of control were tested on three lots of cartridges over 20 days for a total of 120 replicates.

Method comparison data were collected using NCCLS guideline EP9-A[4]. Venous blood samples, collected in lithium or sodium heparin Vacutainer® tubes, and arterial blood samples, collected in blood gas syringes, were analyzed in duplicate on the i-STAT System. A portion of each specimen was centrifuged, and the separated plasma was analyzed on the comparative method.

Deming regression analysis[5] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to the estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Interference studies were based on NCCLS guideline EP7.[6]

*The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[3] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (mg/dL)

Aqueous Control	n	Mean	SD	%CV
Level 1	120	4.6	0.10	2.17
Level 3	120	1.6	0.06	3.75

Method Comparison (mg/dL)

	Hitachi 917	J&J Vitros
n	67	48
Sxx	0.045	0.035
Syy	0.087	0.109
Slope	1.002	1.005
Int't	0.030	-0.109
Sy.x	0.110	0.229
Xmin	0.3	0.5
Xmax	11.2	12.6
r	0.9987	0.9931

Factors Affecting Results*

Interferent	**Effect**
Bromide	100 mg/dL (12.5 mmol/L) bromide will increase creatinine by 0.8 mg/dL (71 µmol/L) from an initial creatinine concentration of 1.0 mg/dL (88 µmol/L).
CO_2	For Crea values below 2 mg/dL: For CO_2 values above 40, the values are increased by 6.9% for every 10 mmHg For CO_2 values below 40, the values are decreased by 6.9% for every 10 mmHg $[Cr]actual = [Cr]istat \ X \ \{ 1 + \ (0.069 \ X \ [(PCO_2-40)/10]) \}$ For Crea values above 2 mg/dL: For CO_2 values above 40, the values are decreased by 3.7% for every 10 mmHg For CO_2 values below 40, the values are increased by 3.7% for every 10 mmHg $[Cr]actual = [Cr]istat \ X \ \{ 1 + \ (0.037 \ X \ [(40 - PCO_2)/10]) \}$
Hydroxyurea (Droxia®, Hydrea®)	Hydroxyurea may cause significant errors in the measurement of creatinine with the i-STAT System. Use an alternative method to measure creatinine when patients have been administered hydroxyurea. See note (1) below for typical uses of this drug and note (2) below for details of the interference.

*It is possible that other interfering substance may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

Notes:

1) Hydroxyurea is a DNA synthesis inhibitor used in the treatment of various forms of cancer, sickle cell anemia, and HIV infection. This drug is used to treat malignancies including melanoma, metastatic ovarian cancer, and chronic myelogenous leukemia. It is also used in the treatment of polycythemia vera, thrombocytopenia, and psoriasis. At typical doses ranging from 500 mg to 2 g/day, concentrations of hydroxyurea in patients' blood may be sustained at approximately 100 to 500 µmol/L. Higher concentrations may be observed soon after dosing or at higher therapeutic doses.
2) For every 100 µmol/L hydroxyurea in the whole blood sample, creatinine will be increased by approximately 1.85 mg/dL (164 µmol/L), up to a whole blood hydroxyurea concentration of at least 921 µmol/L (maximum concentration tested). The magnitude of the bias is independent of the creatinine level over a range of at least 1.0 mg/dL (88 µmol/L) to 12.4 mg/dL (1096 µmol/L).

Acetaminophen up to 20 mg/dL (1.3 mmol/L), ascorbate up to 3.0 mg/dL (0.17 mmol/L), bicarbonate up to 40 mmol/L, bilirubin up to 20 mg/dL (342 µmol/L), calcium up to 5.0 mg/dL (1.25 mmol/L), dopamine up to 13 mg/dL (0.85 mmol/L), methyldopa up to 2.5 mg/dL (118.4 µmol/L), salicylate up to 50 mg/dL (2.8 mmol/L), sarcosine up to 1.0 mmol/L, and uric acid up to 20 mg/dL (1190 µmol/L) were tested and found not to interfere with creatinine results.

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LACTATE/LAC

The enzyme lactate oxidase, immobilized in the lactate biosensor, selectively converts lactate to pyruvate and hydrogen peroxide (H_2O_2). The liberated hydrogen peroxide is oxidized at the platinum electrode to produce a current which is proportional to the sample lactate concentration.

$$\text{L-Lactate} + O_2 \xrightarrow{\text{Lactate Oxidase}} \text{Pyruvate} + H_2O_2$$

$$H_2O_2 \xrightarrow{\text{Platinum electrode}} 2H^+ + O_2 + 2e^-$$

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1] If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for lactate, as part of the i-STAT System, is intended for use in the *in vitro* quantification of lactate in arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for measurement of specific analytes and a buffered aqueous calibrant solution of known concentrations. The calibrant solution contains 2.00 mmol/L (18.0 mg/dL) of lactate.

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference[2] Range (arterial)	Reference[2] Range (venous)
Lactate/Lac	mmol/L	0.30 – 20.00	0.36 – 1.25	0.90 – 1.70
	mg/dL	2.7 – 180.2	3.2 – 11.3	8.1 – 15.3

To convert a lactate result from mmol/L to mg/dL, multiply the mmol/L value by 9.01.

i-STAT measurements are performed on whole blood specimens. The i-STAT System has been calibrated to agree with standard laboratory and reference methods typically performed on whole blood. Therefore, the reference ranges presented above are equivalent to reference ranges derived from whole blood measurements with standard laboratory methods.

The reference range shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

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* The i-STAT System can be configured with the preferred units.

Clinical Significance

Elevated levels of lactate are mainly found in conditions of hypoxia such as shock, hypovolumia, and left ventricular failure; in conditions associated with diseases such as diabetes mellitus, neoplasia, and liver disease; and in conditions associated with drugs or toxins such as ethanol, methanol, or salicylates.[2]

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected using NCCLS guideline EP5-A[3]. Duplicates of each level of control were tested on three lots of cartridges over 20 days for a total of 120 replicates.

Method comparison data were collected using NCCLS guideline EP9-A[4]. Venous blood samples, collected in sodium heparin Vacutainer® tubes, and arterial blood samples, collected in blood gas syringes, were analyzed in duplicate on the i-STAT System. In the plasma study, a portion of each specimen was centrifuged, and the separated plasma was analyzed on the comparative method.

Deming regression analysis[5] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to the estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Interference studies were based on NCCLS guideline EP7.[6]

*The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[3] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (mmol/L)	Aqueous Control	n	Mean	SD	%CV
	Level 1	120	6.35	0.08	1.21
	Level 3	120	0.81	0.03	3.27

Method Comparison (mmol/L)		Radiometer ABL 725 **(whole blood vs. whole blood)**	Hitachi 917 **(i-STAT whole blood vs. Hitachi plasma)**
	n	47	47
	Sxx	0.123	0.084
	Syy	0.136	0.079
	Slope	1.02	1.06
	Int't	0.12	-0.32
	Sy.x	0.18	0.17
	Xmin	0.80	1.77
	Xmax	14.20	14.24
	r	0.998	0.997

Factors Affecting Results*

Special collection procedures are necessary to prevent changes in lactate both during and after the blood is drawn. For steady state lactate concentrations, patients should be at rest for 2 hours and fasting. Venous samples should be obtained without the use of a tourniquet or immediately after the tourniquet is applied. Both venous and arterial samples may be collected into heparinized syringes.

Samples for lactate should be analyzed immediately on drawing as lactate increases by as much as 70% within 30 minutes at 25 °C as a result of glycolysis.[2]

Interferent	**Effect**
Bromide	25 mmol/L (200 mg/dL) bromide will decrease lactate results by 40%.
Cysteine	6.4 mmol/L (101 mg/dL) cysteine will decrease lactate results by 15%.
Hydroxyurea (Droxia®, Hydrea®)	Hydroxyurea may cause significant errors in the measurement of lactate with the i-STAT System. Consider using an alternative method to measure lactate when patients have been administered hydroxyurea. See note (1) below for typical uses of this drug and note (2) below for details of the interference.
Glycolic Acid:	Glycolic acid can cause falsely increased lactate results on the i-STAT System. Preliminary studies indicated that 10 mmol/L glycolic acid increased lactate from 1.45 mmol/L to 3.41 mmol/L. See note (3) for details.

*It is possible that other interfering substance may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

Notes:

1) Hydroxyurea is a DNA synthesis inhibitor used in the treatment of various forms of cancer, sickle cell anemia, and HIV infection. This drug is used to treat malignancies including melanoma, metastatic ovarian cancer, and chronic myelogenous leukemia. It is also used in the treatment of polycythemia vera, thrombocytopenia, and psoriasis. At typical doses ranging from 500 mg to 2 g/day, concentrations of hydroxyurea in patients' blood may be sustained at approximately 100 to 500 µmol/L. Higher concentrations may be observed soon after dosing or at higher therapeutic doses.

2) For every 100 µmol/L hydroxyurea in the whole blood sample, lactate will be increased by approximately 0.16 mmol/L, up to a whole blood hydroxyurea concentration of at least 921 µmol/L (maximum concentration tested). The magnitude of the bias is independent of the lactate level over a range of at least 2.8 mmol/L to 16.0 mmol/L.

3) Glycolic acid is a product of ethylene glycol metabolism. Unexpected increased lactate concentrations caused by glycolic acid may be a clue to the possibility of ethylene glycol ingestion as the cause of an otherwise unknown high anion gap metabolic acidosis. [7, 8] In a study of 35 patients who had ingested ethylene glycol, initial glycolic acid concentrations of 0 to 38 mmol/L corresponded to ethylene glycol levels of 0.97 - 130.6 mmol/L. [7]

Acetaldehyde up to 0.6 mg/dL (0.14 mM), acetominophen up to 20 mg/dL (1.3 mM), acetylsalicylic acid up to 50 mg/dL (2.8 mM), ascorbic acid up to 3 mg/dL (0.17 mM), ß-hydroxybutyric acid up to 202 mg/dL (16 mM), dopamine up to 13 mg/dL (0.85 mM), formaldehyde up to 1.2 mg/dL (0.40 mM), glycine up to 98 mg/dL (13 mM), pyruvic acid up to 2.6 mg/dL (0.24 mM), and uric acid up to 25 mg/dL (1.5 mM) were tested and found not to interfere with lactate results. Hematocrit levels between 25 and 67% were tested and found not to interfere with lactate results.

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CELITE ACTIVATED CLOTTING TIME/ (CELITEACT)

The i-STAT® Celite® Activated Clotting Time test, CeliteACT, is a measure of the time required for complete activation of the coagulation cascade[1]

In traditional ACT tests, coagulation is initiated by mixing a whole blood sample with a particulate activator, and complete activation is indicated when extensive or localized clots form as activated thrombin converts fibrinogen to fibrin. These clots are mechanically detected.

The i-STAT ACT test is similar to traditional ACT except that the endpoint is indicated by the conversion of a thrombin substrate other than fibrinogen and an electrochemical sensor is used to indicate the event of this conversion. The substrate used in the electrogenic assay has an amide linkage that mimics the thrombin-cleaved amide linkage in fibrinogen.

The substrate is H-D-phenylalanyl-pipecolyl-arginine-*p*-amino-*p*-methoxydiphenylamine which has the structure:

Phenylalanine - Pipecolic acid - Arginine -- NH - C_6H_4 - NH - C_6H_4 - OCH_3

Thrombin cleaves the amide bond at the carboxy- terminus of the arginine residue (denoted by the two dashes) because the bond structurally resembles the thrombin-cleaved amide linkage in fibrinogen. The product of the thrombin-substrate reaction is the electrochemically inert tripeptide Phenylalanyl - Pipecolyl - Arginine and the electroactive compound NH_3^+ - C_6H_4 - NH - C_6H_4 - OCH_3 . The formation of the electroactive compound is detected amperometrically, and the time of detection is measured in seconds. The test reports the Activated Clotting Time (ACT) as a whole blood time (WBT) in seconds.

If results appear inconsistent with the clinical assessment, the patient sample should be re-tested using another cartridge.

Intended Use

The i-STAT Celite Activated Clotting Time (CeliteACT) test cartridge, as part of the i-STAT System, is an *in vitro* diagnostic test used to monitor moderate- and high-level heparin therapy through analysis of arterial and venous whole blood samples.

Contents

Each i-STAT CeliteACT cartridge provides a sample collection chamber, sensors to detect the coagulation endpoint and dry reagents necessary to initiate and allow coagulation. These reagents are coated on a section of the sensor channel and include a particulate activator, a thrombin substrate, and stabilizers.

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range
Activated Clotting Time/ACT	seconds	50 – 1000**	74 - 125

*The i-STAT System can be configured with the preferred units.
**The range from 80 - 1000 seconds has been verified through method comparison studies.

Clinical Significance

The ACT is primarily used to monitor a patient's state of anticoagulation due to heparin that is administered during a medical or surgical procedure. It is commonly employed in cardiac catheterization, Percutaneous Transluminal Coronary Angioplasty (PTCA), renal dialysis, hemodialysis, and extra-corporeal circulation during bypass.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected at i-STAT and during clinical trials following a protocol recommended by i-STAT and using plasma control material. Similar results can be expected in future performance studies provided the same experimental design and data analysis procedures are followed.

Plasma Control	n	Mean	SD	%CV
Level 1	329	221 seconds	18 seconds	7.4
Level 2	438	456 seconds	22 seconds	4.8

Method comparison data were collected using a modification of the NCCLS guideline EP9-A[2]. Venous or arterial blood samples were collected in plastic syringes and analyzed in duplicate on the i-STAT System and in duplicate using the comparative methods. All samples were analyzed immediately upon collection. The patient populations in the studies were those in which ACT is routinely used. This includes baseline, heparin-treated, and heparin-reversed samples from from patients undergoing cardiac catheterization and cardiac bypass.

Deming regression analysis[3] was performed on the first replicate of each sample. In the method comparison table, *n* is the number of specimens in the data set, *Sxx* and *Syy* refer to estimates of the imprecision based on the duplicates of the comparative and i-STAT methods respectively, *Sy.x* is the standard error of the estimate, and *r* is the correlation coefficient.

Method comparisons will vary from site to site due to differences in the sample handling, reagent and instrument systems in use, and other site-specific variables.

Cath Lab	Medtronic HR-ACT	Hemochron CA510/FT CA510
n	270	418
Sxx	10.1	19.7
Syy	10.7	13.5
Slope	1.15	0.86
Int'l	-30	-3
Sy.x	32.5	22.5
Xmin	73	63
Xmax	523	763
r	0.848	0.903

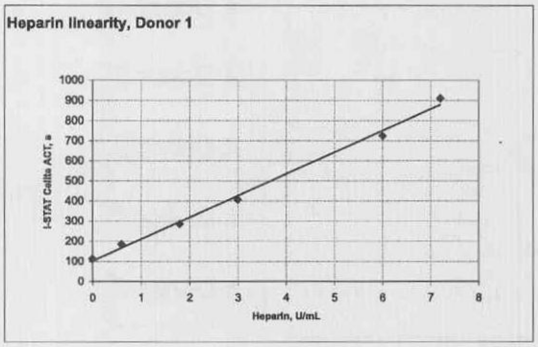
	Hemchron CA510/FT CA510		
CVOR	Site 1	Site 2	Site 3
n	35	30	24
Sxx	15.8	34.2	24.4
Syy	13.0	11.5	20.8
Slope	0.85	1.10	1.19
Int'l	4	-52	-73
Sy.x	43.8	17.4	62.1
Xmin	118	94	125
Xmax	671	735	767
r	0.912	0.952	0.891

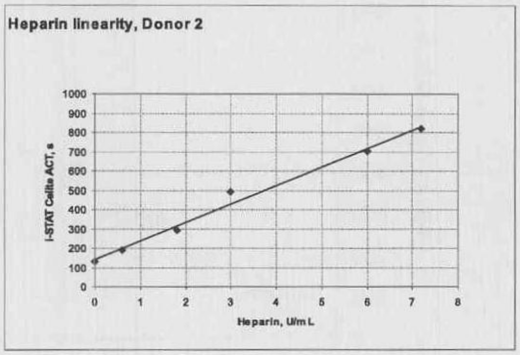
Factors Affecting Results*

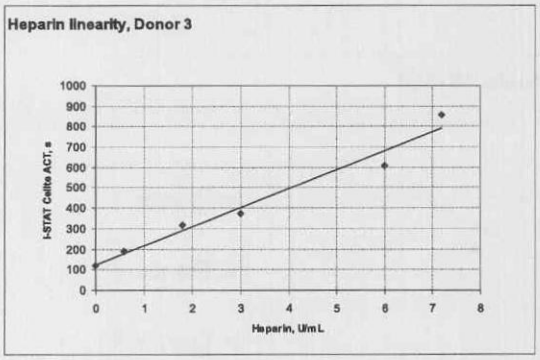
*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

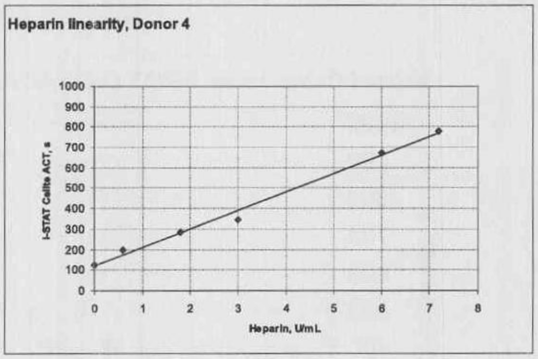
Heparin sensitivity was demonstrated using whole blood samples to which varying concentrations of heparin were added *in vitro*.

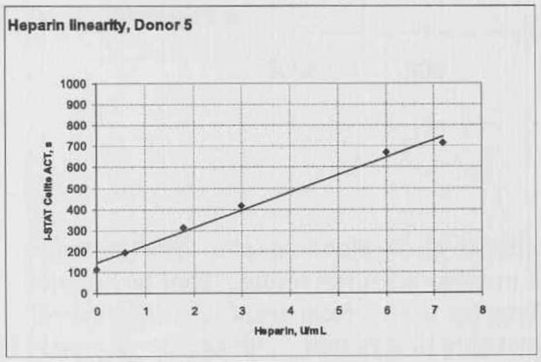
The five graphs below each indicate the response of a different donor with respect to heparin concentration:



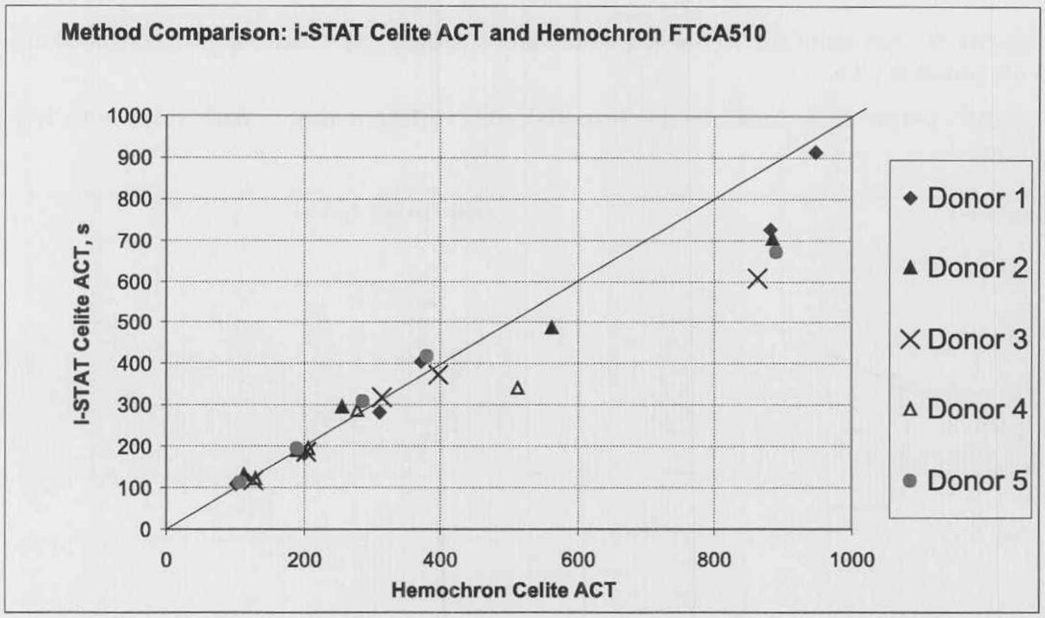


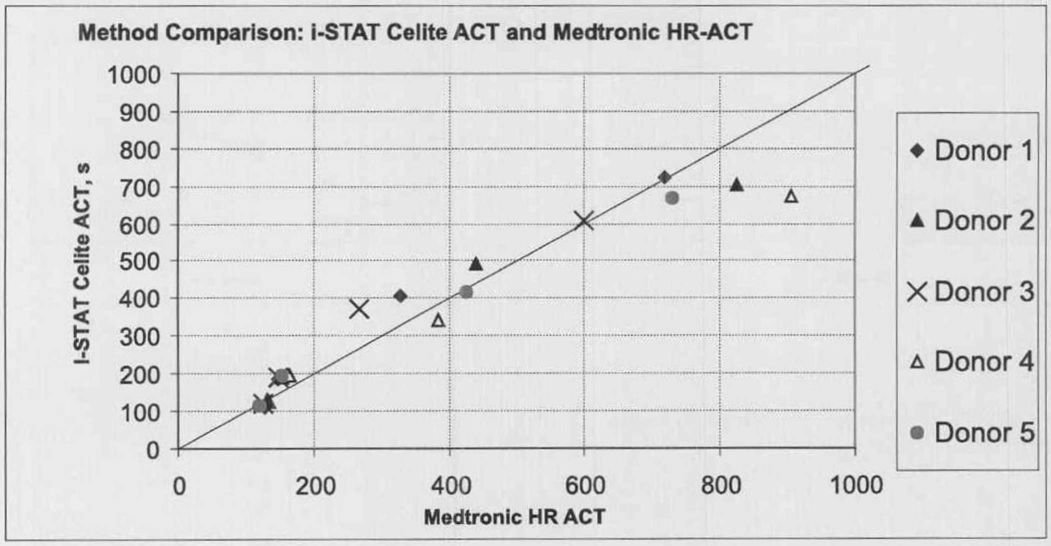






The graphs below indicate the response of the same five donors with respect to the ACT result on the Medtronic HR-ACT and the Hemochron Celite FTCA 510.





Test Limitations

The i-STAT CeliteACT test is to be used with fresh venous or arterial whole blood samples. The presence of exogenously added heparin, citrate, oxalate, or EDTA will interfere with test results. Poor technique in sample collection may also compromise the results. Samples drawn from insufficiently flushed catheters or from traumatic venipunctures may be contaminated with interfering substances. Samples should be collected into plastic syringes or tubes. Collection into glass may prematurely activate coagulation resulting in accelerated clotting times.

The i-STAT ACT test uses Celite brand diatomaceous earth as the activator of the intrinsic pathway. The result may, therefore, be prolonged in the presence of aprotinin.[4] **The test is not recommended for use with patients receiving aprotinin.**

The analyzer should remain on a flat surface with the display facing up during testing. If the analyzer is not level, the ACT result may be affected by more than 10%.

Hemodilution may affect results.

Platelet dysfunction, factor deficiencies, dysprothrombinemias, pharmacological compounds, and other coagulopathies may affect the results of this test.

The i-STAT ACT test is not affected by hematocrit in the range of 20 - 70%, fibrinogen concentration in the range from 100 - 500 mg/dL, or sample temperature from 15 - 37°C.

Storage Instructions

Cartridges in sealed pouches are stable through the expiration date when stored refrigerated at 2 to 8°C and for two weeks at room temperature (18 - 30°C).

Upon removal from refrigeration, a box of 25 cartridges requires one hour equilibration at room temperature before use. Individual cartridges require five minutes equilibration. A cartridge should be used immediately after it is removed from the pouch.

Quality Control

On a daily basis, the performance of all Analyzers in the i-STAT System on site should be verified using the i-STAT Electronic Simulator.

On receipt of new cartridges, verify that the transit temperature was satisfactory using the four-window temperature indicator strip included with the cartridge boxes. From each shipment of cartridges, analyze multiple levels of i-STAT ACT Controls using any verified Analyzer. Instructions for the use of these controls are found in the i-STAT System Manual and should be followed.

For additional information on Quality Control of the i-STAT System, refer to the Quality Control section in this system manual

Specimen Collection and Preparation

The i-STAT $^{\text{Celite}}$ACT test can be performed using venous or arterial samples.

Venipunctures and Arterial Punctures

- Collection technique resulting in good blood flow must be used.
- The sample for testing should be drawn into a **plastic collection device** (either a plastic syringe or plastic evacuated tube).
- The collection device **cannot contain anticoagulants** such as heparin, EDTA, oxalate, or citrate.
- The collection device cannot contain clot activators or serum separators.
- The sample should be immediately dispensed into the sample well of a cartridge.
- If a second measurement is required, a fresh sample must be obtained.

Note: Some experts recommend drawing and discarding a sample of at least 1 mL prior to drawing sample for coagulation testing.[5]

In-dwelling line

- Fluid drip through the line must be discontinued.
- Withdraw 2 mL of blood into a syringe and discard it.
- Withdraw the sample for testing into a fresh **plastic** syringe.
- The collection syringe **cannot contain anticoagulants** such as heparin, EDTA, oxalate, or citrate.
- The sample should be immediately dispensed into the sample well of a cartridge.
- If a second measurement is needed, draw a fresh sample.

Extracorporeal line

- Flush the extracorporeal blood access line by withdrawing 5 mL of blood into a syringe and discard the syringe.
- Withdraw the sample for testing into a fresh **plastic** syringe.
- The collection syringe **cannot contain anticoagulants** such as heparin, EDTA, oxalate, or citrate.
- The sample should be immediately dispensed into the sample well of a cartridge.
- If a second measurement is needed, draw a fresh sample.

References

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3. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method Comparison Analysis," Clinical Chemistry 25:3, 432 (1979).

4. Wang, JS; Lin, CY; Hung, WT; Thisted, RA; Carp, RB. In vitro effects of aprotinin on activated clotting time measured with different activators. Journal of Thoracic Cardiovascular Surgery 104(4):1135-40, 1992.

5. Corriveau, Donna: Fritsma, George (ed.): Hemostasis and Thrombosis in the Clinical Laboratory. Ed, J.B. Lippinncott Company, Philadelphia, 1988, pp 70-71.

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